



produced in association with Euro-Pharmat

Hospital prescription and proper dispensing by community pharmacies - Dressings

Contributors/Authors

This guide is the result of work carried out by the following industry bodies:

Hospitals: Euro-Pharmat, Besançon University Hospital, Clermont Ferrand University Hospital and Strasbourg University Hospital

Industry associations: FSPF - Fédération des Syndicats Pharmaceutiques de France (French Federation of Pharmaceutical Unions),

USPO - Union des Syndicats de Pharmaciens d'Officine (Community Pharmacist Trade Union Association) and SYNPREFH - Syndicat national des pharmaciens des établissements publics (National Union of Pharmacists working in Public-Sector Healthcare Facilities) **Suppliers:** Brothier, Coloplast, Convatec and Owen Mumford

Wholesale distributors: CERP France and OCP Répartition

Introduction

In the context where the patient's health pathway between hospital care and community care is becoming an increasingly important issue, ACLsanté and Euro-Pharmat have come together to set up a committee of experts tasked with drafting a recommendation to facilitate proper dispensing of hospital discharge prescriptions by community pharmacies.

This interdisciplinary framework draws together skills with the potential to make a significant contribution to the proper prescription and dispensing of medical devices to ensure seamless continuity of care for patients when returning home from hospital.

The flow of information between health care professionals and the coordination of those individuals are essential for this care to be properly provided. This recommendation therefore addresses the essential information that must be included in a discharge prescription to ensure proper dispensing by a community pharmacy to improve patient care, at the same time as containing the inherent health care costs.

Without challenging the patient's right to free choice, this addresses only the Hospital / Community Pharmacy circuit.

Purpose

The purpose of this recommendation is to facilitate improved coordination between hospitals and community pharmacies for the benefit of patients and to improve the fulfillment of hospital prescriptions dispensed by community pharmacies (Prescriptions Hospitalières Exécutées en Ville or PHEV). This initial recommendation has been prepared as a reminder of the rules and information essential for proper pharmaceutical

dispensing and optimal patient management following the point of discharge. It presents an outline of the care pathway, the methods used to prescribe dressings for dispensing via community pharmacies, the dispensing of dressings and associated care.

Targets

Simultaneously improving the relevance and efficiency of care and ensuring the proper dispensing of prescriptions requires recommendations to be shared. The work carried out by ACLsanté and Euro-Pharmat is intended for use by all health care professionals, including:

- Pharmacists and their teams
- Doctors
- Nurses
- Masseur-physiotherapists
- Podiatrists

And some of their partners, including:

- Prescription software vendors
- Dispensing software vendors

Assessment and recommendations

The practice of dispensing dressings via community pharmacies has highlighted the random presence of one or other of the following concepts regarding prescriptions:

- · The duration of treatment
- Detailed information regarding the relationship between wound size and dressing size
- The frequency with which dressings should be changed
- Repeat prescriptions for dressings
- Indications regarding the adhesive nature or otherwise of dressings





 The link between the length of the prescription, the rate of wound healing and the date of the next medical appointment does not therefore permit the wound to be reassessed, with the result that inappropriate expenditure may be incurred

As a result, this document contains recommendations for improving the drafting of prescriptions for medical devices used for wound care, and the subsequent dispensing of these health products by community pharmacists.

Prescriptions must also be prepared in accordance with <u>Decree 2012-860 of July 5, 2012</u>, and must also include:

- Patient information, such as full name, gender, date of birth and, if necessary, height and weight
- Prescriber information, such as full name, phone number, RPPS (Shared Directory of Health Care Professionals) number and the FINESS (National Directory of Health and Social Facilities) number of the health institution
- The duration of treatment, taking into account the time of the next medical appointment, so that the prescription can be limited only to that quantity required between wound assessments, thereby reducing the volume of health products dispensed and containing unnecessary expenditure
- Information about the wound(s), including size and location
- · The frequency with which dressings should be changed
- Whether the dressing is adhesive or non-adhesive, and whether a secondary (or retaining) dressing should be prescribed where the primary dressing is non-adhesive
- The list of medical devices, preferably giving their trade names, and regardless of whether they are reimbursable or not Reminder: It is not legally permitted to substitute medical devices prescribed by their trade name, except with the express prior agreement of the prescriber, in the event of emergency and in the best interest of the patient (Article L. 5125-23, paragraph 1, of the French Public Health Code)

The care pathway and its procedures

It is important to describe each step of the care pathway to position the role of each stakeholder in the medical device circuit.

The patient:

The recipient of the care provided. The patient is the focus of the prescription and the final link in the care delivery chain.

The doctor:

The doctor is responsible for patient diagnosis and for writing prescriptions.

The pharmacist

Analyzes the prescription and properly dispenses the required medical devices.

The paramedical professional (most commonly nurses, possibly masseur-physiotherapists and podiatrists)

Delivers care in accordance with medical prescriptions and provides patient follow-up. These professionals are permitted to prescribe under supervision subject to compliance with the conditions set out in the French Public Health Code (CSP).

The prescription

The quality of hospital medical device prescription has a close relationship with the efficacy of outpatient care. The prescription must meet the criteria referred to in <u>Articles R.5132-3 and 5 of the CSP</u> (See table in the 'Summary of prescription procedures, health product dispensing and care provision' section of this document).

Dispensing

Article R. 4235-48 of the French Public Health Code states that the pharmacist must personally supervise every stage in the dispensing process, including:

- Conducting a pharmaceutical analysis of the prescription
- · Providing all necessary information and advice

The dispensing process for which the pharmacist is solely responsible involves the application of appropriate and end-to-end management procedures. Medical devices also form an integral part of good dispensing practices in the context of this recommendation.



Ensure compliance with all current nomenclatures of health products

Nursing care

Within the scope of his/her own role, the nurse carries out the following actions and/or provides the following care to identify risks and ensure the comfort and safety of the patient and his/her family,¹ with particular attention paid to:

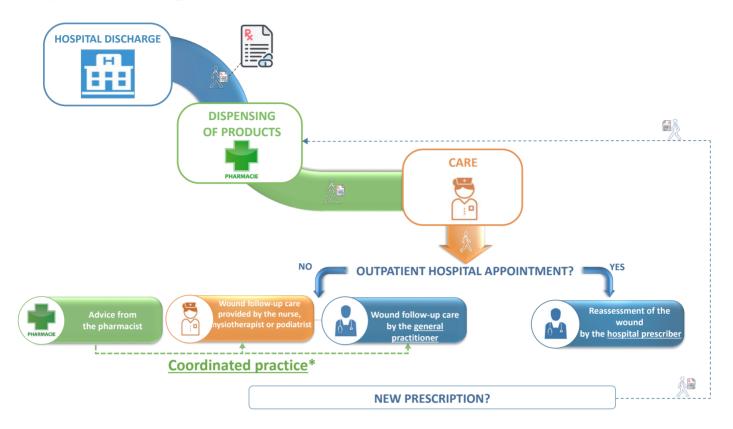
- · The application, monitoring and renewal of dressings
- The publication and monitoring of dressings and bandages other than those specifically referred to in Article R. 4311-7

French Public Health Code R4311-5, points 20 and 21 https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006913892&cid Texte=LEGITEXT000006072665&dateTexte=20040808





Diagram of care pathways



*Coordinated practice²

The term 'coordinated practice' describes a primary or secondary care structure and/or organization within a given geographical area. Designed by health care professionals using two schemes to structure their relationships more effectively and improve coordination³:

Primary Care Teams (PCT): a coordinated organizational structure designed by health care professionals. PCTs bring together a number of health care professionals involved in different aspects of primary care provision with the aim of improving patient health pathways. PCTs are structured around local practice populations, and are united in delivering a health plan shared by all team members.

Regional Health Care Communities (CPTS - Communautés Professionnelles Territoriales de Santé): are integral to population-based schemes, and are formed at the initiative of local care stakeholders, particularly community health care professionals. The plan is designed not only to improve the way which each stakeholder responds to the practice population, but also to provide a structure for responding to health needs in a given geographic area. They differ from the PCTs in that they contribute to the process of responding more

effectively to the needs of a population group already known to PCT members or which is potentially part of their practice population.

Health Care Teams (HCT): are groups of health care professionals that include doctors specializing in one or more areas other than general practice, and who opt to coordinate their care provision with all health care stakeholders (including primary care teams) in a given geographic area, based on a health plan they prepare and agree themselves. The specialist care team works alongside primary care providers to structure health care pathways. Any other form of coordinated practice may be subject to validation by the health authorities.⁴

Reminders of prescription procedures, health product dispensing and care provision

The practices and protocols on completion of medical appointments and at hospital discharge differ widely, making it impossible to put in place a single prescription model that can be adapted to every situation.

These recommendations are intended as guidance to help

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² https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038954739&categorieLien=id

³ http://circulaire.legifrance.gouv.fr/pdf/2016/12/cir_41637.pdf

https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000038886353&cidTexte=LEGITEXT000006072665&dateTexte=20190727





everyone understand the essential information that must be included in all prescriptions, whether regulated under the terms of the French Public Health and Social Security Codes or recommended by the expert members of this group:

Information	Description	References
Delicat identity	The national full name gooder data of high and if valouent, height and unight	R5132-3 7° Public Health Code
Patient identity	The patient's full name, gender, date of birth and - if relevant - height and weight	R165-38 4° Social Security Code**
Prescriber identity	The full name, position and - where applicable - title or specialty of the prescriber, as defined in Article R. 5121-91, their RPPS (shared directory of health care professionals) number where applicable, their professional address (including the word 'France'), their phone number preceded by the international dialing code '+33', their e-mail address, their signature, the date on which the prescription was written, and the name of the health institution or department	R5132-3 1° Public Health Code
Identification of the health institution	Registered name and geographic FINESS (National Directory of Health and Social Facilities) number	Decree 2010-211 Social Security Code
Prescription information	First or repeat prescription for treatment and, where applicable, the nature relative to the long-term condition (ALD - affection de longue durée)	Expert recommendation
Information about the wound and its develop-ment	Size of wound, frequency of dressing changes and, where applicable, the date of the next appointment set by the prescriber for reassessment of the wound	Expert recommendation
	The duration of treatment, number of packaging units and, where applicable, the number of repeat prescriptions	R5132-3 3° Public Health Code
Duration of treatment	Repeat prescriptions cannot cover any period longer than 12 months	R165-36 Social Security Code
	To comply with this condition, retail distributors may not supply a volume of products or services corresponding to a duration of treatment longer than 30 days (one month) in a single delivery	R165-41* Social Security Code
Total duration of prescription and renewal	The total duration of the prescription or repeat prescriptions covering periods no longer than one month, subject to the maximum limit of 12 months	R165-37 Social Security Code
Designation of the health product	The name of the health product prescribed, its frequency of use and the instructions for its use A precise prescription for the medical devices concerned, preferably quoting their trade name, regardless of whether they are registered in the List of Reimbursable Products and Benefits (LPP - Liste des Produits et des Prestations) under their generic or brand name. It is not legally permitted to substitute medical devices prescribed by their trade name, except with the express prior agreement of the prescriber, in the event of emergency and in the best interest of the patient (Article L. 5125-23, paragraph 1, of the French Public Health Code)	R5132-3 2° Public Health Code L5125-23 paragraph 1 Public Health Code
	For reimbursed health products: the description of the product or benefit concerned allowing it to be precisely correlated with the list referred to in Article L. 165-1	R165-38 1° Social Security Code**
Quantity of the health product concerned	The quantity of the health product or the number of packaging units required, based on the regulated duration of prescription	R165-38 2° Social Security Code**
Special conditions applying to the health product	Where applicable, any special conditions applying to the use of the health product or service may govern its inclusion or otherwise in the said list.	R165-38 3° Social Security Code**
Quantity to be provided	To enable funding of health products registered on the list referred to in Article L. 165-1 that are available in different packaging units, the retail distributor provides the patient with the most economical packaging compatible with the information shown on the prescription	R165-39 Social Security Code
Prescription validity	The prescription validity period expires when all the health products and services covered by the total duration of prescription have been dispensed In order for the health product to be reimbursed, it must be dispensed for the first time within 6	R165-40 Social Security Code
Prescription of health products and nursing procedures	months of the prescription date It is recommended that the prescription for nursing care should be on the same document as the health product prescription. Furthermore, information about nursing procedures in terms of wound location and size, the duration and frequency of care and - where applicable - the date of the next appointment can provide valuable guidance for the dispensing of health products, help rationalize the quantities delivered and avoid inappropriate expenditure	Expert recommendation

^{*}However, health products available in packaging corresponding to a duration of treatment exceeding one month may be dispensed for that period up to the maximum limit of the remaining duration of prescription, provided that it is the most economical packaging compatible with the information shown on the prescription.

^{**} LPP reimbursement



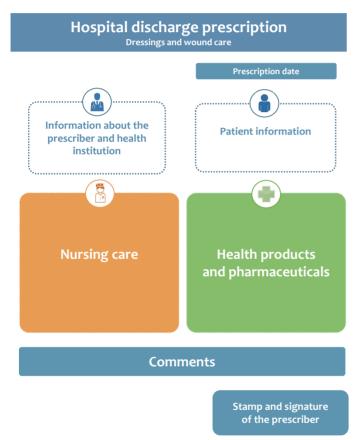
Take account of compliance with the current health product reimbursement listings and of any changes shown on the <u>Ameli website</u>





Essential information for proper prescription of a medical device

The hospital discharge prescription is a guarantee of the quality and safety of the patient's care in the community (as an outpatient). It ensures the transmission of accurate information, proper dispensing by the pharmacist, proper care provision by nurses, and the reimbursement by compulsory health insurance and supplementary health insurance schemes. All the essential information to be included on prescriptions is shown below:



The prescription is in two parts (top copy and duplicate). The duplicate prescription is important, because health care professionnals use it to apply for reimbursement by the Assurance Maladie national health insurance scheme of the cost of products and care.

To guarantee that the cost of health products will be covered by the Assurance Maladie scheme, the name and RPPS number of the patient's referring hospital doctor must be provided for prescriptions written by medical interns.

Prescription support resources

To ensure that hospital discharge prescriptions are appropriate for dispensing via community pharmacies, this recommendation is based on the following resources. although others are available:

'Dressings: indications and recommended uses' published by the French National Authority for Health - April 2011⁵

is classification of dressing indications is accompanied by definitions and types of dressing recommended for each indication listed, and can be valuable in guiding the choices made by health care professionals. Nevertheless, there is still little evidence for using some types of dressing in preference to others. For some indications, no category of dressings can be recommended.

Phase de cicatrisation	Type de plaie	Pansements recommandés
Toutes phases	Chronique	Hydrocolloïdes
(traitement non séquentiel)	Aiguë	Hydrocellulaires ³ Fibres de CMC (hydrofibres) ³
Détersion	Chronique	Alginates 3 - Hydrogels
(traitement séquentiel)	Aiguë	_4
Bourgeonnement	Chronique	Interfaces 5 - Hydrocellulaires 3 - Vaselinés 6
(traitement séquentiel)	Aiguë	Vaselinés ⁶
Épidermisation	Chronique	Interfaces 5 - Hydrocolloïdes
(traitement séquentiel)	Aiguë	Interfaces 5

Situations cliniques spécifiques	Pansements recommandés
Peau fragile (maladies bulleuses)	Interfaces 5
Prévention de l'infection (quelle que soit l'étiologie)	-4
Plaie infectée (quelle que soit l'étiologie)	_4
Plaie hémorragique (dont la prise de greffe)	Algostéril® (alginate)
Epistaxis et autres saignements cutanés et muqueux chez les patients ayant un trouble de l'hémostase	Coalgan [®]
Plaie malodorante (notamment cancers ORL, de la peau ou du sein)	Au charbon activé

- 2. Figurant dans l'arrêté du 16 juillet 2010 et, selon les cas, dans les avis de la Commission.
- Plaies très exsudatives.
- Aucun élément ne permet de recommander dans ce cas un type particulier de pansement. Mepitel®, Urgotul®, Altreet®, Physiotull®® et Hydrotul® (arrêté du 16 juillet 2010).
- Les pansements vaselinés sont largement utilisés et figurent sur la LPPR malgré l'absence de données de haut niveau de preuve démontrant leur efficacité

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https://www.has-sante.fr/upload/docs/application/pdf/2009-01/pansements_synthese_rapport.pdf





	Utilisation des pansements protecteurs, des compresses et du coton					
	Escarres chez l'adulte et chez le sujet âgé pour protéger la peau lorsqu'elle est au stade de la rougeur (urines, macération).	Plaques adhésives minces et transparentes (hydrocolloïdes).				
	Soins des plaies aiguës suturées et des incisions chirurgicales	Pansements adhésifs stériles avec compresse intégrée (support textile).				
	Protection des plaies aiguës légèrement hémorra- giques et/ou exsudatives (sites de cathétérisme intraveineux et incisions chirurgicales).	Pansements adhésifs stériles avec compresse intégrée (support film).				
hémorragiques et/ou	Protection des plaies aiguës peu ou moyennement hémorragiques et/ou exsudatives (sites de cathété-	Compresses stériles de coton hydrophile à bords adhésifs.				
	risme intraveineux et incisions chirurgicales).	Compresses stériles de coton hydrophile non adhérentes.				
	 Plaies aiguës exsudatives (recouvrement de plaie post-opératoire, gynécologie, drainage de plaie, etc.). Plaies chroniques exsudatives : recouvrement de pansements pour drainage des exsudats et protection mécanique de la plaie. 	Pansements/compresses stériles absorbants non adhérents pour plaies productives.				

Utilisation des pansements protecteurs, des compresses et du coton					
 Nettoyage des plaies ou de la peau saine en péri- opératoire (préparation de site opératoire et soins post-opératoires) et pour les plaies aiguës à risque infectieux (notamment brûlures). Confection de pansements en post-opératoire et pour les plaies aiguës à risque infectieux (brûlures, etc.). 	Compresses stériles.				
Nettoyage des plaies en dehors du péri-opératoire. Confection de pansements (plaies chroniques).	Compresses non stériles Note – Compresses stériles pour nettoyer certaines plaies surinfectées ou avec exposition de tissu musculaire ou osseux.				
Nettoyage local de la peau sans plaie ouverte.	Coton hydrophile non stérile.				

Recommandations de la CNEDIMTS pour des pansements évalués après 2007				
Un pansement contenant de l'acide hyaluronique (laluset®, avis du 29 avril 2008).	Usage limité à l'ulcère de jambe			
Trois pansements à l'argent (Cellosorb Ag®, Urgotul Ag® et Urgotul Duo Ag®, avis du 30 septembre 2008).	Usage limité à l'ulcère de jambe *			

^{*} Traitement séquentiel de 4 semaines des ulcères de jambe à caractère inflammatoire, ayant au moins 3 des 5 signes cliniques suivants : douleur entre 2 changements de pansement, érythème péri-lésionnel, œdème, plaie malodorante, exsudat abondant.

'Assistance with discharge prescriptions for dressings and care' published by OMEDIT (Medicinal Products, Medical Devices and Therapeutic innovation Observatory for the Centre Val de Loire region of France)⁶

Optimizing the prescription process for chronic wounds treated in hospitals and the community requires the provision of (initial and ongoing) education and training for doctors and caregivers. Interaction and close collaboration between these professionals help them to apply their theoretical knowledge and experience for the benefit of the patients they care for.

Composition et tarif des SETS DE PANSEMENTS commercialisés en ville (selon la LPP) 1 soin = 1 barquette = 1 blister								
Nom du set			et pour chronique Set de détersion		Set pour plaie post-opératoire (pansements inclus)			
Indications LPP		Plaie chronique avec peau péri- lésionnelle saine		Détersion mécanique pour plaie chronique peau péri-lésionnelle saine		Plaie post-opératoire suturée non infectée		
Surface / Taille		≤ 150 cm²	> 150 cm ²	≤ 150 cm²	> 150 cm ²	PETITE plaie < 5cm	Plaie MOYENNE ≥ 5cm <10cm	GRANDE plaie ≥ 10 cm
Nb barquettes/boîte		1 boîte regroupe 5 barquettes = 5 soins		1 boîte regroupe 3 barquettes = 3 soins				
Accessoire à demander (non obligatoire dans le set)		± 1 paire de ciseaux ± 1 curette		1				
	Pansement « sec » adhésif stérile	absence de pansement			3 /boîte (10x8cm)	3 /boîte (15x9cm)	3 /boîte (25x10cm)	
se	Film adhésif semi-perméable	5 films/boîte (10x15cm)			3 /boîte (12,5x10cm)	3 /boîte (20x15cm)	3 /boîte (20x30cm)	
n de ba	Sacs collecteurs DASRI		5 sac	5 sacs /boîte		3 sacs /boîte		
Composition de base	Compresses stériles	5 compresses /barquette (10x10cm)		10 com /barq (10x1	uette	5 /barquette (7,5x7,5 cm)	5 /barquette (10x10cm)	10 /barquette (10x10cm)
	Pinces stériles		2 pinces	/barquette		2 pinces /barquette		
	Champ absorbant imperméable	1 champ (30x45cm) /barquette			1 champ	(30x45cm) /b	parquette	
Code LPP		134 94 66	138 28 83	133 33 24	138 09 15	132 55 89	136 89 08	131 38 82
Ü	f remboursé / boîte usqu'au 31/12/2016) bit par barquette :	7,46€ soit 1,49€/soin	10,35€ soit 2,07€/soin	7,46€ soit 1,49€/soin	10,35€ soit 2,07€/soin	7,90€ soit 2,63€/soin	9,44€ soit 3,15€/soin	12,04€ soit 4,01€/soin
Renouvellement possible par IDE libéral Remarques La prescription ne peut pas être renouvelée plus de 3 fois, sans nouvelle ordonnance Fournisseurs : Hartmann®, Tetra®, Lohmann®, 3M®, marques de groupements d'achat								



AIDE À LA PRESCRIPTION DE SORTIE DES PANSEMENTS ET DES SOINS DES PLAIES TRAITEES EN VILLE

Optimiser en 9 points clés

- Traiter la plaie selon sa cause et selon l'objectif thérapeutique recherché: curatif ou palliatif?
- Ordonner de façon précise les étapes du protocole de soins + produits nécessaires.
- Privilégier les produits remboursés. Anticiper l'évolution de la plaie, ne pas multiplier les prescriptions et changer sans cesse les produits prescrits. Respecter les recommandations de la HAS, les indications de l'AMM ou de la LPPR.
- 4. Prescrire pour un temps limité un seul type de pansement primaire (la plaie s'améliorant, les quantités consommées peuvent diminuer). Si le pansement ne doit pas être substitué, prescrire en nom de marque avec la mention «non substituable». Prescrire si possible les pansements secondaires en nom générique ex: sparadrap microporeux, bande de crêpe ...
- Informer clairement les différents acteurs des soins en leur écrivant (infirmier, kiné ...)
- Mettre en place les aides aux soins pour les patients dépendants.
- Coordonner les soins, surveiller que les soins et les prescriptions soient adaptés au patient.
- 8. Éduquer le patient et/ou sa famille.
- Renforcer les mesures de prévention secondaire une fois la plaie guérie.

Voir le e-learning en libre accès sur <u>www.omedit-centre.fr/detersion</u>



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Working with dressings requires compliance with basic hygiene practices - hand washing, wound cleaning, etc. - which play a fundamental role in infection prevention.

⁶ http://www.omedit-centre.fr/portail/gallery_files/site/136/2953/5062/6793.pdf





'Assistance with prescribing primary dressings for chronic wounds' published by the Assurance Maladie -February 2016⁷

This resource is intended for use by health care professionals providing follow-up care for chronic wound patients in the community.



La santé progresse avec vous

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¹ https://www.ameli.fr/sites/default/files/Documents/24523/document/memo-pansement-primaire-plaie-chronique_assurance-maladie.pdf





Prescription software:

One important type of resource covered by this publication is the implementation of IT solutions, particularly those software packages designed to provide assistance with prescribing medical devices by all departments of the health institution. Article 32 of the Social Security Finance Bill encourages the increased use of digital technology and sharing of information to improve the quality of care provision.

As part of encouraging this development, this recommendation could contribute to the drafting of a specification.

Dispensing software

Dispensing Software (LAD in French) uses at least one function to record the dispensing of pharmaceuticals and health products or services (prescription analysis, guidance and dispensing) in hospitals (internal pharmacy) and community pharmacies⁸.

Proper use leaflets for Euro-Pharmat dressings

On its website, Euro-Pharmat provides health care professionals with proper use leaflets covering a range of medical devices, including dressings. The purpose of these leaflets is to provide generic technical information for each type of dressing product as an aid to their proper use.

For more information: https://www.euro-pharmat.com/
pansements

ACLsanté product database - dressings available via community pharmacies

The ACLsanté product database contains all the dressings available via community pharmacies. The database contains descriptions and reimbursement data for each of these products. All this information comes directly from the supplier. The suppliers who validate ACLsanté product data sheet are therefore responsible for these data and their use.

Each product is identified by an ACL7 index code, which is used in information systems facilitating interaction between health care professionals.

The ACLsanté makes these product data sheets available

to health institutions in the form of an electronic catalog that can be used for e-Prescription.

All health institutions, their groupings and central purchasing organizations can enter into an information sharing agreement with ACLsanté to obtain access to supplier-validated ACL eCatalogues.

In return, signatory health institutions agree to ask the manufacturers with which they have entered into contracts to update their data in the ACLsanté Product Database.

The end result is that hospital prescribers have a clearer overview of all dressings available via community pharmacies, and can also issue hospital discharge prescriptions in the knowledge that they can be easily dispensed by a community pharmacist. The information required for such prescriptions is as follows:

- · Name of supplier
- · 13-digit product reference code
- · ACL7 index code
- Trade name
- Form
- Size
- Packaging
- LPP reimbursement code
- Indications qualifying for LPP reimbursement
- Medical device class
- · Adhesive or otherwise
- · Discontinued/replaced by

The intention is that this electronic catalog will be made available to prescription software vendors at a future time to maximize interoperability.

For more information: info@aclsanté.org

https://www.ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/ Logiciels-et-applications-mobiles-en-sante/Le-logiciel-ou-l-application-sante-que-je-vais-mettre-sur-le-marche-releve-t-il-du-statut-de-dispositif-medical-DM-ou-de-dispositif-medical-de-diagnostic-in-vitro-DM-DIV/Exemples-de-logiciels-et-applications-mobiles-illustrant-le-positionnement-reglementaire



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Reference documents and databases

- French Social Security Code Decree 2012-860 of July 5, 2012 on the terms and conditions for prescribing and issuing products and benefits included on the list provided for in Article L. 165-1 of the French Social Security Code. JORF July 7, 2012. Available from:
 - https://www.legifrance.gouv.fr/affichTexte.do?cidTexte = JORFTEXT000026152057&categorieLien=id
- French Public Health Code Article R5132-3 defines the information to be included on prescriptions. Available from:
 - https://www.legifrance.gouv.fr/affichCodeArticle.do?id Article=LEGIARTI000028393053&cidTexte=LEGITE XT000006072665&dateTexte=20131228
- French Public Health Code Order of March 20, 2012, establishing the list of medical devices that may be prescribed by nurses. JORF March 30, 2012. Available from:
 - https://www.legifrance.gouv.fr/affichTexte.do?cidTexte =JORFTEXT000025592708&categorieLien=id
- French Public Health Code Order of January 9, 2006 establishing the list of medical devices that may be prescribed by masseur-physiotherapists. JORF January 13, 2006. Available from:
 - https://www.legifrance.gouv.fr/affichTexte.do?cidTexte =JORFTEXT000000635168&categorieLien=id
- French Code of Public Health Order of July 30, 2008 establishing the list of topical treatments for external use that may be prescribed and applied by chiropodists/podiatrists, and the list of dressings that may be prescribed and applied by chiropodists/ podiatrists. JORF of August 2, 2018. Available from:
 - https://www.legifrance.gouv.fr/affichTexte.do?cidTexte =JORFTEXT000019278274
- French Public Health Code Article R4235-48 defines the dispensing process. Available from:
 - https://www.legifrance.gouv.fr/loda/id/ JORFTEXT000019278274/
- French Social Security Code Decree No. 2017-584
 of April 20, 2017 setting the terms and conditions
 governing implementation of the CAQES (contrat
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www.aclsante.org

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Glossary

Medical device: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products are also be deemed to be medical devices:

- Devices for the control or support of conception
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.⁹

FINESS: Fichier National des Etablissements Sanitaires et Sociaux (National Directory of Health and Social Facilities)

LPPR: Liste des Produits et des Prestations (List of Reimbursable Products and Benefits)

Primary dressing: dressing applied in direct contact with the wound

Secondary dressing: dressing that covers the primary dressing

Acute wound: a wound expected to heal within a period time deemed normal, i.e., with no local or general factor that may potentially delay healing. Etiologies include, but are not limited to, burns, grafts, grafting and post-surgical healing wounds, cuts, punctures, bites, scratches, stings, abscesses and pilonidal sinus abscesses (sacrococcygeal cyst removal), frostbite and deep dermabrasion¹⁰

Chronic wound: a wound with a prolonged healing time as a result of one or more factors with the potential to delay healing. Depending on the etiology, a wound is considered chronic after 4 to 6 weeks of delayed healing. Etiologies include leg ulcers, pressure sores, diabetic wounds, cancerous wounds, amputation stumps, and extensive burns with prolonged healing times¹¹

RPPS: Répertoire Partagé des Professionnels de Santé (Shared Directory of Health Care Professionals)

- https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:32017R0745&from=FR
- 10 https://www.has-sante.fr/upload/docs/application/pdf/rapport_evaluation_pansements_.pdf
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Summary

In the context where the patient's health pathway between hospital care and community care is becoming an increasingly important issue, ACLsanté and Euro-Pharmat have come together to set up a committee of experts. Its goal is to make a significant contribution to the proper prescription and dispensing of medical devices to ensure seamless continuity of care for patients when returning home from hospital. This recommendation addresses the essential information that must be included in a discharge prescription to ensure proper dispensing by a community pharmacy to improve patient care, at the same time as containing the inherent health care costs. It presents an outline of the care pathway, the methods used to prescribe dressings for dispensing via community pharmacies, the dispensing of dressings and associated care.

KEY WORDS

ACLsanté Product Database - CPTS (Regional Health Care Communities) - Detersion - Dispensing - Medical Device - MD - Home - Efficiency - Primary Care Team - Health Care Team - Assessment - Coordinated Practice - Proper use of medicines leaflets - Hospital - Nurse - Dispensing Software - Prescription Software - Masseur-physiotherapist - Prescription - Dressing - Care pathway

- Pharmacy Acute wound Chronic wound Podiatrist
- Recommendations Prescription Recommendation Nurse care - Community





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Annex I

"Sample template of a prescription form for dressings issued prior to patient discharge", published by Clermont-Ferrand University Hospital

	SUPPORT DE PRESCRIPTION	DE PANSEMENTS POUF	 		
CLERMONT PETHAND	LA SORTIE DU PATIENT		FBU.001 Version 9/12/ 2019		
ETABLISSEMENT DE SANTE	DU PRESCRIPTEUR	PRESCRIPTEUR			
Raison sociale :		Nom:			
Adresse :		Prénom			
		Service			
		Identifiant RPPS:			
N° FINESS :		(ou coller l'étiquette du prescripteur,			
		Téléphone :			
IDENTITE DU PATIENT :		PRESCRIPTION			
Nom :		Date de la prescription :			
Prénom :			Date de la prescription : Durée : 7 jours 15 jours Autres		
Date de naissance :		Date prochaine consultation :			
Date de Haissance I minimi		à renouveler fois :			
(ou coller l'étiquette patient).		☐ Initiation de traitement			
			Renouvellement ou modification par le médecin ou l'IDE		
☐ Soin en rapport avec une	ALD	a Kenodvenement od modines	tion par le medecin ou i ibe		
	LA PLAI				
□Plaie 1 :Site		nie 2 :Site	Taille: cmx cm		
	□Plaie 3 :Site	Taille: cmx cm			
	L'ACTE INFIRMIER : à pratiquer par l'IDE au	cabinet ou au domicile			
Nettoyage : savon liquide gant de toilet	2) pansement long et complexe(AMI 4) doux et sans parfum a à l'eau du robinet be propre compresses				
Rinçage sérum physiologiq Détersion de la plaie : No	ue (NaCl 0,9%) et séchage de la peau péri-lésio on	nnelle par tamponnement / Sécher s	oigneusement entre les orteils		
	ii Détersion douce et atraumatique □ Avec and	esthésie locale : 🗆 Lidocaïne 5% spray	NR 🗆 Autres		
	□ Avec □ p	oince a curette a bistouri			
Soins de la peau péri-lésion	nnelle :				
□ Détersion des croûtes / so	quames / hyperkératose péri-lésionnelle				
□ Crème émolliente en cou	che mince :(préciser le nom) :	D Autres	••••		
	LES PRODUITS DE SANTE				
Pansement primaire (au con	tact de la plaie) : Ne doivent pas être associés sur une	même plaie à l'exception des pansements	s au charbon actifs et des		
	especter les durées d'application pour une bonne évoi				
- 1-Désignation : (classe, épaisseur, forme) Pansement adhésif stérile Pansement à l'acide hyaluronique					
	lle :Qtité		Pansement gras		
	aisseur, forme)		Interface		
	e : Qtité		Pansement au charbon actif		
	aisseur, forme)		Pansement à l'argent		
- Adhésif : □Oui □ Non Taill		☐ Alginate			
Pancament cacandaire ou	dispositif de maintien (recouvre le pansement prima	sira di mfanonaimi :			
	Sparadrap		Quantité :		
Autros produkts :					
Autres produits: Compresses Taille: 07,5x7,5 cm 10x10 cm Tissées Non tissées Quantité: 18 Boite de 25 sachets					
Compresses Falle: 07,59	déterrier avec guestre - Set plaie post enérat	antite: 1 Boite de 25 sachets	Nombro :		
	détersion avec curette Set plaie post-opérate		Nombre :		
	(NR) = Pince(NR) Quantité :		4.		
□ NaCl 0,9% en unidoses 5mL (NR) / unidoses 10mL (NR) / poche 50mL / poche 100mL / flacon 250 mL Quantité :					
LES PRODUITS DE SANTE LIES AUX SPECIFICITES					
□ Ablation d'agrafes □ Ote agrafe (NR) Quantité :					
□Compression/contention veineuse □ indication□Quantité□Quantité□Quantité□					
□Bandes allongement long □Légère □ Classe 2 □ Classe 3 □ Bandes allongement court □ Classe 3 □ Classe 4					
□Chaussette: □ classe 2 □ classe 3 □ classe 4 □ Pansement multitype:					
DBas classe 2 -classe 3 -classe 4 -classe 4 -classe 5 -classe 5 -classe 5 -classe 6 -classe 6 -classe 7 -c					
	COMMENTAIRES SIGNATURE				
Commentaires					
Remettre un formulaire signé à chaque acteur (Patient, Pharmacien, infirmier,) NR : Non remboursé					

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Annex II

"Sample template of a prescription form for dressings and wound care issued prior to patient discharge", published by OMEDIT Centre Val de Loire

Modèle de PRESCRIPTION DE SORTIE « PANSEMENTS ET SOINS DES PLAIES »

PRESCRIPTEUR	PATIENT			
Nom :	Nom :			
Prénom :	Prénom :			
Téléphone : [,	Date de naissance :			
Service :	N° d'assuré : [] [] [] [] [] [] []			
Identifiant RPPS*:	☐ Soins en rapport avec une ALD			
(*répertoire partagé des professionnels de santé)				
ÉTABLISSEMENT DE SANTÉ DU PRESCRIPTEUR	PRESCRIPTION			
Raison sociale :	Date de la prescription :			
Adresse :	Durée: jours à renouveler : fois			
	Initiation du traitement à domicile			
N° FINESS** géographique :	Renouvellement ou modification			
(* *fichier national des établissements sanitaires et sociaux)				
Le traitement d'une plaie se fait par le traitement de la cause	e, la plaie ne cicatrise pas grâce aux seuls pansements			
SOINS INFIRMIERS (1 ord	lonnance par plaie)			
rayer les mots ou expressions inutiles sur fond grisé				
- Site de la plaie :				
- Faire pratiquer par IDE au cabinet / à domicile, pansement(s) toutes le	s heures pendant jours y compris dimanches et fériés			
 Pansement courant (AMI 2) / Pansement long et complexe (AMI 4) 				
- Ablation de fils / Ablation d'agrafes Préciser nombre de fils/points : 10 ou				
Lavage - Bain de pie				
- Laver: au savon liquide doux et sans parfum / à l'eau du robinet / au NaCl	0.9% avec : gant toilette propre / compresse			
- Rincer au sérum physiologique (NaCl 0.9%)				
 Sécher la peau péri-lésionnelle par tamponnement / Sécher soigneusement 	t entre les orteils			
Détersio	o <u>n</u>			
- Pas de détersion / Détersion douce et non traumatique avec : pince / cur				
sous lidocaine 5 9	% sol. pulv : 5 pulvérisations (attendre au moins 2 min. avant geste)			
Soins de la peau pér	ri-lésionn elle			
- Détersion des croûtes / squames / hyperkératose péri-lésionnelle				
 hydratation de la peau péri-lésionnelle par crème émolliente en couche mir 				
PRODUITS DE				
Pansement primaire « Les pansements primaires (au contact direct de la plaie, en dehors de ceux au Respecter les durées d'application pour une bonne évolution de la plaie, le confort du patient et une réduction				
Désignation				
(famille classe, épaisseur) Adhésif : Oui / Non Forme :	Qté : Qté :			
Pansement secondaire (si nécessaire, il recouvre le pansement primaire)				
Désignation				
Autres produits :	1.5 - 1			
- Compresses Sachets de: 2 / 5 / 10 Taille: 7.5x7.5 cm / 10x10 cm	Qté de sachets :			
- Sparadrap / Adhésif :				
- Set plaie chronique / Set détersion avec curette / Set plaie post opératoire Nb de plateaux :				
- Lidocaïne 5 % sol. pulv. (Xylocaïne * nébuliseur) (hors AMM, non remboursé) Qté :				
- NaCl 0.9% en unidoses 5mL (non remb.) / unidoses 10mL (non remb.) / poche 50mL / poche 100mL / flacon 250mL / spray (non remb.) Qté:				
- Bande de maintien (ou similaire) :				
- Bande de contention à allongement court :				
- Bande de compression élastique (classe, étalonnée, marque) :				
- Mi-bas / Bas de contention (toille, classe, marque):				
- Ote agrafe (non remb.) Qté:				
Commentaires - Signature				
Rythme des soins :				
Clanabura				
Signature :				
Remettre un formulaire signé à chaque acteur (patient, infirmier, pharmacien, kinésithé	rapeute, prestataire,) Proposé par : http://www.omedit-centre.fr			