

**Dagsorden for 7. møde i
Netværk for Forebyggelse af Medicineringsfejl
torsdag d. 14. april 2011
kl. 13-16
i Lægemiddelstyrelsen
mødelokale Salix**



- Velkomst
- "Sidste nyt" ved Lægemeddelstyrelsen
- Cytostatika – patientsikkerhed i kræftbehandling, ved Henriette Lipczak fra Kræftens Bekæmpelse
- *Pause*
- Introduktion af Patientombuddet, ved Jørgen Hansen
- Nyt fra arbejdet med "Risikosituationslægemidler"
- Dato for næste møde – 10. november 2011
- Eventuelt



Sidste nyt fra Lægemiddelstyrelsen

- Mangel på Spirocort inhalationsspray
 - AeroBec fra Teva har været på det danske marked med engelsk mærkning
- Ændringer i gamle betegnelser for lægemiddelformer
 - "Mikstur" udgået (dec. 2006)
 - "Rektal væske" udgår (2011)



Standard Term databasen

- Termer i Dansk Lægemiddelstandarder er hentet fra Standard Term databasen, der er fælles for EU.
- Termer:
- Lægemiddelformer
- Patient Friendly Terms (tidl. Short Terms) mærkes *
- Administrationsveje
- Lukkere, beholder, doseringsudstyr m.v.
- Kombinationstermer



Standard Terms

- ☐ Dosage forms
- ☐ Patient friendly (formerly Short) Terms
- ☐ Routes and Methods of administration
- ☐ Containers, closures and delivery devices
- ☐ Combined Terms

Status definitions

Each term in the Standard Terms database is assigned a status according to the following definitions.

Current: the Standard Term is approved for use.

Deprecated: the Standard Term is not approved for use; it is not physically removed from the database and is maintained to cover legacy data.

Rejected: the Standard Term has been rejected during evaluation and is not approved for use; it is included in the database in order to avoid the submission of new requests for the term.

Decisions pending

28 March 2011

The following term has been adopted in principle by the Standard Terms Working Party and is pending approval:

'Prolonged-release suspension for injection'

Recent decisions

21 February 2011

The following decisions that were accepted in principle by the Standard Terms Working Party have now been adopted by the European Pharmacopoeia Commission and entered into the Standard Terms database:

'Oromucosal spray' dosage form deprecated

'Oromucosal spray' patient-friendly term accepted

'Oromucosal spray, emulsion' dosage form accepted

'Oromucosal spray, solution' dosage form accepted

'Oromucosal spray, suspension' dosage form accepted

'Multidose container with pump' container accepted

General information

As of 22 February 2006, the Standard Terms database is published using new software. Revisions are no longer indicated at the bottom of the term translations, but on a language-per-language basis. Because of this very significant change, revisions made until 8 December 2005 are no longer indicated in the database.

The database can now be searched on a single language basis. The hit list shows the term in the chosen language.

Revision dates can also be searched, but the dates have to be entered in the inverted format, for example 2006-02-22. In order to search only for the terms added as described under 'Revision history', search for the revision date and specify English as the language.

Guidance and change requests

Information on how to make the best use of the Standard Terms database and the form for sending change requests can be found in the Download section of the EDQM website <http://www.edqm.eu/>. To locate the relevant documents, use the web browser search function to search for 'Standard Terms' on the Download page, or use these direct links: [Introduction & Guidance for Use](#), [Standard Term form](#). Please note, requests for modifications or additions to the Standard Terms database can only be received from Member States, the EMA or the EU.

Further instructions for use

Revision history

Since the first on-line publication of this database, originally based on the 4th Edition of the printed version of the Standard Terms for dosage forms, routes of administration and containers, the following changes have been made:

28 March 2011

Deprecated 1 combined term ('Inhalation impregnated pad') and reinstated 1 combined term ('Inhalation vapour, impregnated pad'); added 4 combined terms ('Prolonged-release suspension for injection in pre-filled syringe', 'Powder for use in drinking water/milk', 'Oral solution in sachet', 'Oral suspension in sachet'); corrected 1 route/method of administration in English ('In drinking water or milk use' corrected to 'In drinking water/milk use'); corrected 1 dosage form definition ('Syrup'); added 1 rejected term ('Frozen solution for sealant').

21 February 2011

Deprecated 1 standard term, added 3 replacement standard terms and 1 patient-friendly term; added 1 new standard term.

29 November 2010

Deprecated 9 combined terms, added 1 replacement standard term and 8 combined terms.

19 November 2010

'Status definitions' and 'Decisions pending' sections added to this page.

11 October 2010

Deprecated 14 combined terms, added 7 replacement combined terms.

6 October 2010

Added 1 new standard term, 2 new combined terms and 1 rejected combined term.

3 September 2010

Added 1 new standard term.

2 September 2010

Added 3 new standard terms and 1 combined term.

9 August 2010

Added 4 new combined terms, 1 deprecated combined term and 1 rejected combined term.

21 July 2010

Added 3 new standard terms.

22 June 2010

Added 6 new standard terms.

17 June 2010

Added 2 new combined terms.

16 June 2010

Added 4 new combined terms and 2 new standard terms.

15 June 2010

Added 2 new combined terms.

7 June 2010

Posted a new version of the introduction and the form for requesting changes to the database (see the download section of our web site <http://www.edqm.eu/>).

22 April 2010

Added 4 new standard terms and 5 new combined terms.

Oral væske = Oral liquid

- Definition fra Standard Term database:
- Liquid single-dose or multidose preparation intended for oral use. It consists of a liquid active substance per se. Each dose from a multidose container is administered by means of a suitable device such as a measuring spoon.
- DLS: Oral væske er en betegnelse, der kun anvendes for de meget få aktive stoffer, f.eks. levertran og amerikansk olie, der administreres direkte oralt uden nogen form for formulering.



Oral væske * = Oral liquid *

- Patient Friendly Term dækker over
- Oral opløsning
- Oral suspension
- Oral emulsion
- JF. DLS: PF term må kun anvendes, når der ikke er forvekslingsmuligheder.
- PF term må ikke anvendes til magistrelle lægemidler, da det ikke andre steder fremgår, hvad den egentlige lægemiddelform er. Magistrelle lægemidler skal mærkes med fuld lægemiddelform.



Rectal liquid findes ej i STT

- Enema * = Klysma (Dansk) *, dækker over
- Rektalvæske, opløsning = Rectal solution
- Rektalvæske, suspension = Rectal suspension
- Rektalvæske, emulsion = Rectal emulsion



Standard Terms

- Dosage forms
- Patient friendly (formerly Short) Terms
- Routes and Methods of administration
- Containers, closures and delivery devices
- Combined Terms

Hit list

Language	Term	Revised
ID number	20050	
English	Enema	
Created on	before 5 March 2009	
Status	Current	
Domain	H+V	
French	-	
Italian	Clistere	17/06/2009
Spanish	Enema	17/06/2009
Portuguese	Enema	17/06/2009
Romanian	-	
German	Klistier	17/06/2009
Dutch	Klyzma	
Danish	Klyzma	17/06/2009
Norwegian	Rektalvæske	17/06/2009
Icelandic	Endaparmsvökvi	17/06/2009
Swedish	Rektalväska	17/06/2009
Finnish	Peräruiske	17/06/2009
Estonian	Rektaalvedelik	22/04/2010
Turkish	Rektal sıvı	17/06/2009
Kazakh	Клизма	03/02/2010
Hungarian	Klizma	17/06/2009
Czech	Klyzma	17/06/2009
Slovak	Rektálna kvapalina	17/06/2009
Slovenian	Rektalna tekočina	17/06/2009
Croatian	Tekućina za rektum	17/06/2009
Serbian	Klizma	16/03/2006
Polish	Wlew doodbytniczny	17/06/2009
Lithuanian	Klizma	
Latvian	Klizma	
Russian		
Bulgarian	Клизма	17/06/2009
Macedonian	Ректална течност	17/06/2009
Greek	Υποκλυσμός	17/06/2009
Albanian	Klizmë	01/12/2008
Maltese	Enema	17/06/2009
Chinese		
Linked Term(s)	Rectal solution Rectal suspension Rectal emulsion	

Eksempel på forvekslingsag



Eksempel på forvekslingsssag



Lægemedelstyrelsens netsted

- Ny liste på hjemmesiden: Kontrol af lægemidler og indlægssedler (vinter 2011) -[link](#)
- Utilsigtede hændelser –nyheder -[link](#)

