

Guide to the application form for humane single and humane general extradition permit

Updated December 16, 2022

If you have NemLog-In (in the form of an employee signature), you can easily send the application form to the Danish Medicines Agency digitally. We encourage the use of digital applications because it facilitates our administrative work for the benefit of case processing. However, you also have the option of sending or faxing the application to:

Danish Medicines Agency

Dispensing licenses

Axel Heides Gade 1

2300 Copenhagen S

E-mail: [Send an e-mail](#) (can receive encrypted e-mail)

Tel.: 44 88 95 95 (Monday – Friday 9 am – 3 pm)

Fax: 44 88 91 17

General information

The application form must be used when applying for a dispensing permit in accordance with section 29, subsection of the Danish Medicines Act. 1.

You can **either** apply for permission for the treatment of a single patient (individual permission) **or** for the treatment of a group of patients (general permission) of e.g. a hospital ward/practice.

ATTENTION! If you wish to apply for permission to use a **medicinal product manufactured by a master (pharmacy-manufactured)**, you **do not** need to apply for a dispensing licence. You must, on the other hand, apply for a permit from the Danish Medicines Agency's Section for Pharmacies, Affiliates & Medicine Prices for the magisterial manufacture of a medicinal product. This must only be done in special cases where you are prescribing a masterfully produced drug that has the same therapeutic effect as a drug already on the market. You can apply and read more [here](#).

Need for urgent treatment

In special cases where the patient has an urgent need for treatment, we can process applications for a **humane single**

delivery permit as urgent cases and provide a response to the application within 24 hours (on weekdays). In that case, the application must be clearly marked " **URGENT** " after the applicant's name.

Link

Application forms for human simple dispensing authorization and human general dispensing authorization: [Application for dispensing authorization for medicinal products for humans](#) .

NOTE:

Only these forms can be used for applications for distribution permits.

How to fill out the form digitally

- The form is opened via the link above.
- Here you will be greeted with NemLog-In, which is required to access the form.
- Alle felterne udfyldes så godt som muligt. Felter markeret med * er obligatoriske.
- I rubrikken ”**Præparatet skal anvendes til følgende indikation**” skal der entydigt stå, hvilke(n) sygdom(me) eller hvilke(t) symptom(er), du ønsker at anvende præparatet mod.
- I rubrikken ”**Begrundelse for valg af præparat**” skal det tydeligt fremgå, hvorfor markedsførte alternativer i Danmark ikke kan anvendes. Endvidere skal du redegøre for tidligere behandling samt resultatet af denne behandling. Er der ikke plads nok til begrundelsen, kan du vedlægge begrundelsen som bilag.

Sådan udfylder du skemaet, hvis du ikke kan indsende digitalt

- Formularen tilgås via [Ansøgning om udleveringstilladelse - Enkelt human](#) og [Ansøgning om udleveringstilladelse - Generel Human](#)
- Alle felter udfyldes. Felter markeret med * er obligatoriske.
- I rubrikken ”**Præparatet skal anvendes til følgende indikation**” skal der entydigt stå, hvilke(n) sygdom(me) eller hvilke(t) symptom(er), du ønsker at anvende præparatet mod.
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- Underskriv formularen inden du sender den til Lægemiddelstyrelsen scannet med e-mail: [Send en mail](#) på fax 4488 9117. Hvis du indsender den pr. mail så vedhæft ansøgningen i én samlet indscannet fil.

Præparater, der viser sig ikke at være Lægemiddelstyrelsen bekendt

Hvis Lægemiddelstyrelsen ikke kender det ansøgte lægemiddel, skal du sende dokumentation for:

- Præparatets fremstilling
- Sammensætning
- Holdbarhed
- Emballage
- Præparatets effekt på den ansøgte indikation
- Oplysninger om præparatets godkendelsessituation i andre lande, særligt EU.
- Hvem der er ansvarlig for evt. import af præparat til Danmark.

Hvordan modtager du svar?

Svar på ansøgning om udleveringstilladelse afhænger af, hvorfra du søger:

Hospitaller

If you apply from a hospital, you will receive a reply in the department's function mailbox. You must ensure that you pass on the distribution authorization to the right parties.

Practitioners and dentists

Please state the company's CVR number if you are applying from private practice. We send the answer to the company's Digital Post, which can be accessed via virk.dk. You must pass on a copy of the dispensing permit to the patient and/or the pharmacy.

Validity

A distribution permit can be valid for up to 5 years. If you then wish to extend the permit, you must send a new application. Feel free to submit applications for extension of the distribution permit one month before the current distribution permit expires.

When you issue a prescription for the preparation, the patient must have a copy of the dispensing permit for use by the pharmacy.

Did you get answers to your questions?

Yes	No
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The Danish Medicines Agency
Axel Heides Gade 1
2300 Copenhagen S
Email: dkma@dkma.dk

Contact the Danish Medicines Agency
44 88 95 95 (9 a.m. - 3 p.m.)

The Danish Medicines Agency is part of the
Ministry of the
Interior and Health.

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