Information on the use of medicines outside the approval (off-label use)

Name of the patient

Date

Doctor providing information

Dear
As part of your medical treatment, we would like to use medications that are not approved for this treatment by the regulatory authorities.

What is off-label use?

"Off-label use means the use of drugs outside of their marketing authorization." Before a drug can be brought onto the market, the pharmaceutical manufacturer must submit an application for approval to the authorities. This application includes detailed evidence from studies showing that the drug is effective in the intended use while having relatively acceptable side effects. For example, if a drug for pain is to be approved, studies must have shown that it helps well against pain. However, if this drug is now also used for other purposes, e.g. for breathlessness, it is referred to as "off-label use". The reasons for the lack of approval can be very different. Examples are

- lack of interest of pharmaceutical manufacturers in a marketing authorisation (the marketing authorisation procedure is time-consuming and cost-intensive);
- lack of or insufficient evidence of efficacy in certain therapeutic uses.

The lack of a marketing authorisation therefore does not mean that it is a bad or ineffective medication. In palliative medicine we use drugs relatively regularly off-label. This is often due to the fact that we do not have an approved drug available for more common uses in palliative medicine, or that approved drugs are in some cases not effective or not sufficiently effective.

What are benefits and risks?

The marketing authorisation of a drug does not allow any conclusions to be drawn about what else it can be used for. The off-label use of a drug helps to fill therapeutic gaps. This means that we gain further therapeutic options if we do not have any licensed drugs available. In some cases, there is already a lot of scientific and clinical evidence for the efficacy of a drug outside its approval, e.g. morphine for breathlessness. At the same time, however, the risks of off-label therapy cannot always be assessed just as well as the risks of treatment with licensed drugs. The less experience there is with a particular treatment, the more difficult it is to assess the exact effects and the risk of unwanted side effects.

What is being treated?

We would like to use the following drug(s) off-label for your treatment:

Active ingredient & available product	Dose and route of administration	Treatment goal

Reasons for the selection of these drug(s) are

- ☐ approved therapy options exhausted
- ☐ approved therapy options not appropriate
- ☐ no approved treatment options available
- ☐ treatment recommended in guideline(s)
- ☐ other:

What side effects and risks are to be expected?

Basically, the same side effects are to be expected as with the designated use of the drugs. Information on this can be found in the package insert. If you have any further questions, seek medical advice or consult your local pharmacist. Depending on the mode of administration, the following side effects may also occur:

Active ingredient & available product	Possible side effects/risks

Do I have to be particularly attentive to certain things during therapy?

Irrespective of the type of therapy, please do not hesitate to contact the medical staff or the responsible nurse or consult your local pharmacy if you have any questions about your drug therapy or are insecure.
You should be particularly attentive to the following:

Consent

I was informed orally about possible risks of the treatment by my attending physician and my questions were answered.
In this context, a special focus was placed on:

☐ I reject the suggested treatment. The possible implications have been explained to me.
☐ After an adequate time for reflection, I agree to the planned drug treatment.

Place, date, time

Signature physician

Signature of the patient or authorised representative