LMU KLINIKUM DER UNIVERSITÄT MÜNCHEN

ZENTRALSTELLE OFF-LABEL-USE

KLINIK UND POLIKLINIK FÜR PALLIATIVMEDIZIN

# Documentation Off-Label-Drug Use

## For off-label-use with little or no scientific evidence to date

Please document the following details as completely as possible (use additional sheet if necessary).
Return the sheet to info@arzneimittel-palliativ.de after completion of treatment.

Start of off-label-use (date):

**by email**

If required, treating physician (for further questions):

## 1. Drug-related information

1.1. Active ingredient & available product used off-label
1.2. (Off-label-)indication
1.3. Previous treatment attempts (active substance or reason why they are no longer used)
1.4. Type of off-label-use (e.g. route of administration, dose, indication, etc.)
1.5. Basis for decision-making

## 2. Patient-related data (please do not mention a name or date of birth!)

2.1. Age:

2.2. Primary diagnosis:

2.3. Current drugs (optionally under 6.):

## 3. Monitoring of therapy

3.1. Which therapeutic goal should be achieved?
3.2. Monitoring parameters:

| **Monitoring parameters for side effects** | | |
|---|---|---|
| Parameter | Interval for checking | Checked by |
| *e.g. pruritus with rectal application* | *1x/day* | *Nurse* |
| | | |
| | | |
| | | |
| | | |

| Monitoring parameters for effects | | |
|---|---|---|
| Parameter | Interval for checking | Checked by |
| *e.g. dyspnea* | *3x/day* | *Physician* |
| *e.g. serum levels* | *Trough serumlevels prior to 3. dose* | *Physician* |
| | | |
| | | |
| | | |
| | | |

## 4. Informed consent

Information for patient or authorized representative

☐ yes, written consent

☐ yes, verbal consent

☐ no, Reason:

## 5. Treatment effect

5.1. Was the treatment goal achieved (effect strength 0 = no effect until 10 = treatment goal completely achieved)?
5.2. If applicable, details of serumlevels incl. time of collection
5.3. In which time frame was the effect observed?
5.4. What side effects (positive and negative) occurred?
5.5. Will the treatment be continued? ☐ yes ☐ no
5.6. If no: why not?

## 6. Additions