## *VI.2 Elements for a Public Summary*

### VI.2.1 Overview of disease epidemiology

Although pain – including moderate to severe pain - is a very common symptom, data on the number of people in a given population who are reported to suffer from pain are inconsistent. For example, estimates of the number of people suffering from long-lasting (chronic) pain vary widely and typically range between 10 and 30% of the adult population, although rates ranging from 2 to 55% have been reported. This wide variation may reflect true differences between populations, but also the use of different definitions and classifications of chronic pain, for example duration of more than three or more than six months, and differences in assessment methods.

### VI.2.2 Summary of treatment benefits

Current standards of treatment of pain

The World Health Organization (WHO) recommends a "pain ladder" for managing pain: If pain occurs, there should be oral administration of drugs in the following order:

- Nonsteroidal anti-inflammatory drugs such as Diclofenac or Ibuprofen, a class of drugs that provide pain relieving, fever-reducing effects and inflammation-reducing effects
- then, as necessary, mild narcotic drugs (opioids)
- then strong narcotic drugs (opioids) such as morphine or oxycodone

This three-step approach is effective in the majority of patients.

Where the medicinal product fits in the therapeutic armamentarium

Oxycodone is a strong pain killer and is only used for the treatment of severe pain, which cannot be adequately managed with other medicinal products.

### VI.2.3 Unknowns relating to treatment benefits

See Part VI: VI.2.4 Important missing information.

### VI.2.4 Summary of safety concerns

**Important identified risks**

| Risk | What is known | Preventability |
|---|---|---|
| **Respiratory depression** (insufficiency to obtain enough oxygen via breathing) | Disturbance of breathing caused by strong pain killers such as oxycodone can range from decrease in breathing rate to breathing arrest. It may be life-threatening and result in death. | Careful dosing as directed in the patient information leaflet and careful supervision of the patient are necessary. |

| | | |
|---|---|---|
| **Drug withdrawal and dependence**<br>(reactions related to the withdrawal the and addiction to oxycodone) | Physical dependence is common to strong pain killers (this does not equal addiction). Abruptly stopping these medications will cause a withdrawal response. Such withdrawal response may as well occur dramatically reducing opioid drugs after prolonged use. Withdrawal symptoms can include restlessness, watery eyes (lacrimation), running nose, yawning, perspiration, chills, muscle pain, dilation of the pupil and irregular heartbeat, irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate or heart rate. These symptoms can occur 8 – 16 hours after the last dose and can last up to 72 hours or longer. | In patients who no longer need the product, it is recommended to taper the dose gradually in order to prevent symptoms of withdrawal. |

| **Risk** | **What is known** | **Preventability** |
|---|---|---|
| **Drug Abuse, misuse and diversion**<br>(injecting oxycodone in blood vessels/intentionally taking to much oxycodone/ illegal dispensing) | Oxycodone like all opioids has the potential to be abused, misused and illegally distributed.<br>Abuse is the self-administration of medications to alter one's state of consciousness. This is an intentional use of a medication.<br>Misuse (noncompliant use) is the intentional or unintentional use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs.<br>Diversion is the redirection of a prescription drug from its lawful purpose to illicit use. | Oxycodone 5 – 20 mg film-coated tablets must be swallowed whole and must not be crushed, divided or chewed.<br>Patients treated with strong pain killers such as oxycodone should be supervised carefully |

## Important potential risks

**None**

## Missing information

| Risk | What is known |
|---|---|
| **Use in children <12 years of age**<br>(Safety in children younger than 12 years) | Safety and effectiveness of oxycodone have not been established in children younger than 12 years. Therefore, oxycodone is not recommended for children and adolescents under 12 years of age. Depending on age and body weight, the risk for overdose may be increased in younger children. |

| Risk | What is known |
|---|---|
| **Safety and efficacy of use during pregnancy and breastfeeding** | Experience with the use of oxycodone during human pregnancy is insufficient and does not allow a final assessment. Use of oxycodone during early pregnancy was reported to be associated with defects of the infant's heart. Infants born to mothers with longer-term intake of oxycodone may exhibit withdrawal symptoms following birth (e.g. irritability, hyperactivity, abnormal sleep pattern, high-pitched cry, tremor, vomiting, diarrhea, weight loss, and failure to gain weight) and are at increased risk of sudden infant death. Oxycodone crosses the placenta and may produce disturbance of breathing in newborns. Oxycodone has been detected in maternal milk. Accordingly, oxycodone should not be taken by pregnant or breastfeeding women. |

### VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of P roduct Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures. The Summary of Product Characteristics and the package leaflet for the products under review can be found i n the Module 1.3.1 of this application. This medicine has no additional risk minimisation measures.

### VI.2.6 Planned post authorisation development plan

Not applicable

### VI.2.7 Summary of changes to the Risk Management Plan over time

| Date and version of significant change to the RMP | New safety concern (added / removed / changed) | New study (added / finished) | Summary of changes to the risk minimisation activities*. |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 18/11/2015<br>Version 01 | Important identified risks<br>- Respiratory depression<br>- Drug withdrawal syndrome and dependence<br>- Drug abuse, misuse and diversion<br>Important potential risks<br>- Overdose<br>- Medication errors<br><br>Missing information<br><br>- Safety in children younger than 12 years<br>- Safety and efficacy of use during pregnancy and lactation | Not applicable | First Version |
| 03/03/2016<br>Version 02 | Important identified risks<br>- Respiratory depression<br>- Drug withdrawal syndrome and dependence<br>- Drug abuse, misuse and diversion<br>Important potential risks<br>N/A<br><br>Missing information<br>- Use in children <12 years of age<br>- Use during pregnancy and breastfeeding | Not applicable | Update as requested in the Day 70 PrAR by the RMS (DE) |