Desitin Arzneimittel GmbH

Explanations on editorial changes performed in the SmPC and PL

Summary of Product Characteristics

Changes concerning diverse sections

Throughout the text, orthographic and typing errors were corrected. Furthermore adaption according to the QRD template was performed throughout the document.

Section 2
This section was updated according to the current excipients guideline.

Section 4.2
Subheadings were included according to QRD template. Further subheadings for certain special patient groups were added to facilitate access to specific information. Due to implementation of subheadings the following passages had to be moved within section 4.2, as they apply to all patients. No change in information.

> *Treatment should be as short as possible. The lowest dose that can control the symptoms should be used.*
> *The patient should be reassessed regularly and the need for continued treatment should be evaluated, especially in case the patient is symptom free.*

Information on dose reduction in patients with chronic respiratory insufficiency was moved from section 4.4 to the more appropriate section 4.2. No change in information.

> *Patients with chronic respiratory insufficiency*
> *A lower dose is recommended for patients with chronic respiratory insufficiency due to the risk of respiratory depression.*

Information on administration was moved to section 4.2 due to QRD template. This information was previously placed in section 6.6 of SmPC. No change in information.

Section 4.4
The section was revised and restructured by collecting information in the following subsections:

- Paediatric populations
- Specific patient groups
- Development of tolerance
- Development of dependence
- Drug discontinuation effects/Withdrawal symptoms
- Amnesia
- Psychiatric and paradoxical reactions
- Information on excipients

Subheadings were implemented to facilitate finding of information. This required repositioning of information within the section. Repositioned information includes information on the use in cases of loss or bereavement, use in the paediatric population, reduced dose in the elderly, use in high risk patients. No change in information.

The following information was repositioned to the more appropriate section 4.2 (see above):

> *Elderly should be given a reduced dose (see posology). A lower dose is also recommended for patients with chronic respiratory insufficiency due to the risk of respiratory depression.*

According to the SmPC guideline, for medicinal products with a major influence on driving and using machines, respective warnings should be also mentioned in section 4.4. Therefore, the section was amended with the paragraph “Driving and using machines” containing a warning in line with information already included in section 4.7.

Section 4.5

The section was restructured by implementing subsections on Pharmacokinetic and Pharmacodynamic interactions. Therefore, it was necessary to reposition existing information within the subsection. This applies to the following interactions:

- theophylline/smoking
- potentiation of phenytoin effect
- isoniazid
- disulfiram
- cimetidine, omeprazole (reduced clearance of benzodiazepines)
- oral contraceptives
- rifampicin (increased clearance of benzodiazepines)

Since the interaction with alcohol and its effects are addressed in several sections throughout the SmPC, references to other relevant section were included.

Section 4.6

The section was revised and restructured by collecting information in the following subsections:

- Women of childbearing potential
- Pregnancy
- Breast-feeding
- Fertility

Subheadings were implemented to facilitate finding of information. This required repositioning of information within the section.

Examples of possible withdrawal symptoms in neonates were added: “(e.g. hyperactivity, irritability)”.

According to the SmPC guideline, “If there are no fertility data at all, then this should be clearly stated”. Therefore, the subsection “Fertility” was newly introduced, stating that “No clinical data on fertility are available”.

Section 4.8

In line with the recommendations of the SmPC guideline, a summary of the safety profile was added at the beginning of section 4.8.

Definitions of frequency were added in line with MedDRA frequency convention.

The undesirable effects already mentioned in section 4.8 were check for and allocated to the correct system organ class according to MedDRA. The order of SOCs was corrected according to MedDRA convention.

In line with section 4.7 of the current SmPC, administration of the medicinal product may lead to impaired concentration. To be consistent throughout the SmPC, impaired concentration was also added as undesirable effect to section 4.8.

Chest pain was already mentioned as undesirable effect in the current approved PL of the medicinal product. To be consistent throughout the documents, it was added to the SmPC as well.

Section 4.9

Information only referring to management of intoxication after overdose by oral ingestion was deleted, since the SmPC applies to a medicinal product for rectal administration.

Section 5.2

To specify the information on volume of distribution, the unit for the existing value was amended to “l/kg **body weight**”. No change in information.

Section 6.6

Information on administration was moved to section 4.2 due to QRD template. No change in information.

Sections 11./12.

Since these sections are not applicable for the medicinal product, the headings were deleted.

Package Leaflet

Changes concerning diverse sections

The Package Leaflet was adapted to the current changes in the SmPC, using patient friendly wording as appropriate.
Throughout the text, orthographic and typing errors were corrected. Furthermore adaption according to the QRD template was performed throughout the document.