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Statens legemiddelverk

OTC use in Norway for ferrous (II) sulphate ATC-code: B03AA07

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing ferrous(II) sulphate, It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing ferrous (II)-sulphate. In addition, an overview of the approvable strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway is included.

- The proposed OTC indication and posology in the OTC package leaflet and labelling must be covered by the information approved in the corresponding SmPC.

Preparations for oral use, iron (II) up to 100 mg per unit or 9 mg/ml.

1. Package leaflet

1.1 Indication

Til voksne og barn: mot jernmangel, etter anbefaling fra lege eller jordmor.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1–2 tablets, 1 drop, 1 suppository, 20 ml…). The total daily dose can be divided into several dosages, depending on the formulation.

Behandlingen kan starte først etter at diagnosen har blitt stilt av lege eller jordmor.

Voksne og barn over 12 år: 100 – 200 mg daglig.

Ikke del <legemiddelform>. Svelg <legemiddelform> hel sammen med minst ½ glass væske. Du må ikke ta <produktnavn> i liggende stilling.

Behandlingstid:
Behandlingen bør fortsette til du har normale blodverdier. Dette tar normalt 10 – 20 uker eller lengre.

2. Labelling

2.1 Indication

State the indication as in the PIL. If the full indication is stated on the back panel of the package, the following abbreviation can be used on the front panel:

Mot jernmangel etter anbefaling fra lege.

2.2 Posology

State the dosage as in the PIL.

2.3 Other information

Not applicable

3. Content of the pack

The table below presents the highest level of the terms for approvable pharmaceutical forms, if possible. For example: the term "tablets" includes all types of tablet formulations as for example film coated tablets or chewable tablets. For active substances where some pharmaceutical forms are exempt from approval due to safety concern, this is stated explicitly below the table.

Pharmaceutical form	**Maximum strength**	**Maximum pack size**
Tablets (including chewable tablets)	100 mg	250
Oral solution, drops	9 mg/ml	250