Approved: 16.06.2014
Revised: 07.01.2020

Statens legemiddelverk

OTC use in Norway for famotidine/magnesium hydroxide/calcium carbonate, ATC-code: A02BA53

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing famotidine/magnesium hydroxide/calcium carbonate. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing famotidine/magnesium hydroxide/calcium carbonate. 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 , famotidine up to 10 mg, magnesium hydroxide up to 165 mg, calcium carbonate up to 800 mg per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 16 år: korttidsbehandling av halsbrann og sure oppstøt.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1-2 tablets, 1 suppository, 20 ml…). The text below include the posology and the necessary information included for the most commonly used pharmaceutical dose forms.

Voksne og barn over 16 år: ta 1 dose (tilsvarende 10 mg/165 mg/800 mg av famotidin/magnesiumhydroksid/kalsiumkarbonat) ved behov for å lindre plager. Du må ikke ta mer enn 2 doser (tilsvarende 20 mg/310 mg/1600 mg av famotidin/magnesiumhydroksid/kalsiumkarbonat) i løpet av 24 timer.

<Produktnavn> skal ikke brukes sammenhengende i mer enn 2 uker. Ønsker du lenger bruk må dette avtales med lege.

Kontakt lege innen 2 uker dersom plagene blir verre eller ikke har blitt bedre.

Kommer plagene ofte tilbake er det viktig at du kontakter lege.

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 halsbrann og sure oppstøt

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, capsules. Granules or oral solution in sachet	Famotidin 10 mg Magnesiumhydroksid 165 mg Kalsiumkarbonat 800 mg	24