

Meditonsin[®]

GLOBULES

Globules

For babies from 7 months, children and adults.

Aconitinum D5, Atropinumsulfuricum D5 and Mercurius cyanatus D8

Please read all of this leaflet carefully before you start taking this medication because it contains important information for you. Always take this medication exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Meditonsin[®] Globules are and what they are used for
2. What you should know before you take Meditonsin[®] Globules
3. How to take Meditonsin[®] Globules
4. Possible side effects
5. How to store Meditonsin[®] Globules
6. Contents of the pack and other information

1. WHAT MEDITONSIN[®] GLOBULES ARE AND WHAT THEY ARE USED FOR

Meditonsin[®] Globules are a homeopathic medicine for use in colds.

Therapeutic indication

The therapeutic indications are those associated with the homeopathic drug picture. These include acute inflammation of the throat, nose and pharynx. You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE MEDITONSIN[®] GLOBULES

Do not take Meditonsin[®] Globules:

- if you are allergic to Aconitinum Dil. D5, Atropinumsulfuricum Dil. D5, or Mercurius cyanatus Dil. D8.

Warnings and precautions

Talk to your doctor or pharmacist before taking Meditonsin[®] Globules.

Important Information about certain other ingredients of Meditonsin[®] Globules

This pharmaceutical contains sucrose. Please take Meditonsin[®] Globules only after consulting your doctor if you know you are intolerant to certain sugars.

There is inadequately documented experience of the use of Meditonsin[®] Globules for babies less than 7 months old. It should therefore not be used in this patient group. Meditonsin[®] Globules should only be given to babies aged between 7 and 12 months after consultation with a doctor.

If symptoms persist or new symptoms appear, or if there are signs of fever or respiratory distress, please talk to your doctor.

Taking Meditonsin[®] Globules together with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or are planning to take any other medicines. Interactions with other medicines have not been reported.

Taking Meditonsin[®] Globules together with food, drinks, and alcohol

The effects of homeopathic medicines can be impaired by generally damaging life-style factors and by the consumption of tea, coffee, alcohol, tobacco, etc.

Pregnancy, breast-feeding, and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and ability to use machines

Meditonsin[®] Globules have no influence on the ability to drive and use machines.

3. HOW TO USE MEDITONSIN[®] GLOBULES

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has discussed with you. Check with your doctor or pharmacist if you are not sure.

For adults and adolescents from 12 years of age on:

In acute situations, adults and adolescents from 12 years take 5 globules every 30 minutes to 1 hour, at the most 6 times daily.

For babies from 7 months to 1 year of age: After consultation with a doctor, take up to 4 times daily, one globule each time.

For children from 1 year of age on: Take up to 6 times daily one globule each time.

For children from 6 to 12 years of age: Take up to 6 times daily one to two globules each time (at the most 11 globules per day).

Method of administration

Allow the globules to dissolve in the mouth. They do not have to be taken at mealtimes.

Duration of treatment

Meditonsin[®] globules should be taken as early as possible.

Administration may exceed one week only after consultation with a doctor or a therapist experienced in homeopathy. Please talk to your doctor or pharmacist if you feel that the effects of Meditonsin® Globules are too strong or too weak.

If you take more Meditonsin® Globules than you should:

After accidental overdose, some of the ingredients may cause nausea, vomiting and diarrhoea. In this case, consult a doctor immediately.

If you forget to take Meditonsin® Globules:

Do not take a double dose if you forgot the previous dose but continue with the dose as directed above.

If you stop taking Meditonsin® Globules:

A return of the symptoms is to be expected.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects

Increased salivation may occur after use of Meditonsin® Globules. In this case, stop taking the medicine.

Hypersensitive reactions (i.e. pruritus, urticaria) can occur. In this case, stop taking the medicine.

Note: When taking homeopathic medicines, the current symptoms can worsen temporarily (initial worsening). In this case, stop taking the medicine and ask your doctor for advice.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly to

Bundesinstitut für Arzneimittel und Medizinprodukte
Abt. Pharmakovigilanz
Kurt-Georg-Kiesinger Allee 3
53175 Bonn
Website: www.bfarm.de

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDITONSIN® GLOBULES

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the carton after "Verwendbar bis:". The expiry date refers to the last day of that month.

Storage conditions:

No particular storage conditions are required.

Do not use Meditonsin® Globules longer than 6 months after first opening and do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Meditonsin® Globules contain:

The active substances are:

10 g of pellets (size 5) contains:

Aconitinum Dil. D5 [HAB, Regulation 5a, solution D2 with 86% ethanol (m/m)] 10 mg

Atropinumsulfuricum Dil. D5 50 mg

Mercurius cyanatus Dil. D8 40 mg

Aconitinum D2 and D3, Atropinumsulfuricum D2 and D3 and

Mercurius cyanatus D4 – D6, each potentised with a mixture of 94% (m/m) ethanol / 85% glycerol / purified water (ratio 5:10:85); Aconitinum D4,

Atropinumsulfuricum D4 and Mercurius cyanatus D7, each potentised with 73 % (m/m) ethanol.

Also contains sucrose.

What Meditonsin® Globules look like and the contents of the pack:

The globules are contained in a brown glass bottle with an LDPE dropper insert and a PP screw-cap with an HDPE tamper-proof ring. One original pack contains 8 g of globules.

Marketing authorisation holder and manufacturer

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Unofficial translation of the German package leaflet.

