

Package leaflet: Information for the patient

Glitinum hard capsules

Powdered feverfew

Traditional Herbal Medicinal Product

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you feel worse or do not feel better after 2 months.

What is in this leaflet

1. What Glitinum is and what it is used for
2. What you need to know before you take Glitinum
3. How to take Glitinum
4. Possible side effects
5. How to store Glitinum
6. Contents of the pack and other information

1. What Glitinum is and what it is used for

Glitinum is a traditional herbal medicinal product for the prevention of migraine headaches after serious conditions have been excluded by a medical doctor.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

2. What you need to know before you take Glitinum

Do not take this medicine:

- if you are allergic to feverfew or other plants of the Asteraceae (Compositae) family or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Children and adolescents

This medicine shall not be used in children and adolescents under 18 years of age due to lack of adequate data.

Other medicines and Glitinum

In the event of contacting a doctor or a qualified health care practitioner, remember to tell that you are taking or recently have taken this non-prescriptive medicine.

No effects of using other drugs at the same time as this medicine have been reported.

Glitinum with food, drink and alcohol

No effects of taking food, drink or alcohol at the same time as this medicine have been reported.

Pregnancy, breast-feeding and fertility

Use of this medicine during pregnancy and lactation is not recommended, due to the absence of sufficient data. Safety during pregnancy and breast-feeding has not been established. However, traditional experience suggests that *Tanacetum parthenium* may stimulate menstrual flow and induce abortion.

No information is available on the effects of feverfew on male and female fertility.

Driving and using machines

Glitinum has no or negligible influence on the ability to drive and use machines.

You should drive a vehicle or carry out dangerous work only when you can do it safely. Medicines may influence your capability to drive or carry out dangerous work. Read the information provided in the package leaflet carefully. Ask your doctor or pharmacist for advice if you are unsure.

3. How to take Glitinum

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

The recommended dose for adults and elderly is: 1 capsule daily.

Swallow the capsule whole (with water or a little liquid). Do not chew the capsules.

Consult a doctor if migraine headaches recur after using the medicinal product for 2 months, or if the symptoms worsen during the use of the medicinal product. It usually takes up to 2 months to obtain an effect.

Use in children and adolescent

The use in children and adolescents under 18 years shall not take place.

If you take more Glitinum than you should

If you have taken more Glitinum than you should, or if children take this medicine by accident, please contact your doctor or hospital for advice. [Relevant information from the following text is included only in the Finnish, Norwegian and Swedish leaflets.] You can also call the following number:

In Finland: Myrkytystietokeskus (tel. 09 471 977).

In Norway: Giftinformasjonen (tel. 22 59 13 00).

In Sweden: Giftinformationscentralen (tel. 112).

If you forget to take Glitinum

Do not take a double dose to make up for a forgotten dose. Take the next dose as usual.

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.

Gastrointestinal disturbances have been reported. The frequency is not known: Frequency cannot be estimated from the available data.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[Country name]

[Contact details]

[Contact details — line 2]

[Contact details — line 3]

[Contact details — line 4]

[Contact details — line 5]

5. How to store Glitinum

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 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. Contents of the pack and other information

What Glitinum contains

- The active substance is powdered feverfew.

One capsule contains 100 mg of powdered *Tanacetum parthenium* (L.) Schulz Bip., (feverfew) herba corresponding to 100 mg of dried herb of feverfew.

- The other ingredients are dextrin; silica, colloidal anhydrous; talc; magnesium stearate; titanium dioxide E171; hypromellose.

What Glitinum looks like and contents of the pack

White opaque hard capsule (19.4x7.0 mm). The capsule contents are beige-greenish.

The capsules are packed in blister packs.

This medicine is available in packs of 30, 60, 90 and 120 hard capsules. Not all pack sizes may be marketed.

Registration Holder

Sana Pharma Medical AS
Philip Pedersens vei 20
1366 Lysaker
Norway

Manufacturer

Wiewelhove GmbH
Dörnebrink 19
49479 Ibbenbüren

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This leaflet was last revised in <{MM/YYYY}>

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