

Package leaflet: Information for the patient

Giduxa soft capsules

Devil's claw root dry extract

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 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 2 weeks of treatment (mild digestive disorders) or 4 weeks of treatment (minor joint pain). See section 3.

What is in this leaflet

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

1. What Giduxa is and what it is used for

Giduxa is a traditional herbal medicinal product used in adults for the relief of:

- Minor joint pain
- Mild digestive disorders (such as bloating, flatulence, and temporary loss of appetite).

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

Giduxa contains dry extract from devil's claw root.

2. What you need to know before you take Giduxa

Do not take this medicine:

- If you are allergic to devil's claw root (also known as *Harpagophytum*), peanut, soya or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from ulcers in your stomach or intestines.

Warnings and precautions

Talk to your doctor before using Giduxa, if you have:

- joint pain accompanied by swelling of joints, redness or fever;
- gallstone problems.

If the symptoms worsen during the use of this medicinal product, you should contact a doctor.

Children and adolescents

The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.

Other medicines and Giduxa

Possible effects of concomitant administration of other medicines have not been studied.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also includes Giduxa.

Giduxa with food, drink and alcohol

There are no known effects of taking Giduxa with food or drink.

Pregnancy, breast-feeding and fertility

In the absence of sufficient data, the use of Giduxa during pregnancy and breast-feeding is not recommended. Possible effects on fertility have not been studied.

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 using machines

Giduxa does not affect 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. Ask your doctor or pharmacist for advice if you are unsure.

Giduxa contains soya oil, lecithin (phospholipids from soya beans), lactose and sorbitol

If you are allergic to peanut or soya, do not use this medicinal product. This medicine contains 27 mg sorbitol in each capsule. Furthermore, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Giduxa

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.

Adults:

The recommended dose is 2 capsules twice daily.

Maximum daily dose: 4 capsules.

Take the capsules with a glass of water.

If the symptoms persist longer than 4 weeks while using Giduxa for the relief of minor joint pain or 2 weeks for the relief of mild digestive disorder, a doctor or a qualified health care practitioner should be consulted.

If you take more Giduxa than you should

If you have taken more Giduxa than you should, or if children take this medicine by accident, please contact your doctor, hospital or pharmacy for advice. Bring the package with you. **You can also call the following numbers:**

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

In Iceland: Eitrunarmiðstöð (sími 543 2222).
In Norway: Giftinformasjonen (tel. 22 59 13 00).
In Sweden: Giftinformationscentralen (tel. 112).

If you forget to take Giduxa

If you forget to take a capsule, take the next dose at the usual time. It does not matter if you forget to take a dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Giduxa

You can stop taking this medicine at any time.

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. The following side effects have been reported:

- Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain.
- Central nervous system disorders: headache, dizziness.
- Allergic reactions: rashes, hives, swelling of the face.

The frequency of these effects is not known.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[Only country-specific information applicable to a particular leaflet is provided, selected from Appendix V.]

[To be completed nationally]

5. How to store Giduxa

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.

Do not store above 30°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 Giduxa contains

- The active substance is a dry extract from devil's claw root.

Each capsule contains 225 mg of extract (as dry extract) from *Harpagophytum procumbens* DC. and/or *Harpagophytum zeyheri* Decne. (devil's claw), radix (equivalent to 990-1125 mg of devil's claw root). Extraction solvent: ethanol 60% (V/V).

- The other ingredients are lactose monohydrate, hydrated colloidal silica, refined soya-bean oil, refined coconut oil, fractionated palm kernel oil, yellow beeswax, lecithin (phospholipids from soya beans), butter fat, gelatin, glycerol, partially dehydrated liquid sorbitol (E420), yellow iron oxide (E172).

What Giduxa looks like and contents of the pack

Oval (15x10 mm), light brown, soft capsules. The capsule contents are dark brown.

Giduxa is available in blister packs containing 30, 60, 90 or 120 capsules. Not all pack sizes may be marketed.

Registration Holder

[To be completed nationally]

Manufacturer

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