Package leaflet: Information for the user

<Product name> film-coated tablets
Extract of Devil´s claw

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

Always use this medicine exactly as described in this leaflet or as your doctor or other health care professionals have 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 other health care professionals. 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 within 4 weeks.

What is in this leaflet

1. What <Product name> is and what it is used for

<Product name> is a traditional herbal medicinal product used for relief of pain in mild joint abrasion (osteoarthritis).

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

2. What you need to know before you use <Product name>

Do not use <Product name>
- if you are allergic to Devil´s claw or any of the other ingredients of this medicine (listed in section 6).
- if you ever had or have stomach ulcer or duodenal ulcer.
- if you are pregnant or breastfeeding.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using <Product name>, if you have gallstone problems or cardiovascular disease.

If your joint pain is accompanied by swelling of joints, severe motion pain, redness or fever, you should be examined by a doctor.

Children and adolescents
<Product name> is not recommended for children and adolescents under 18 years of age.

Other medicines and <Product name>
The effects of concomitant administration of other medicines are not studied.

Tell your doctor or other health care professionals if you are taking or have recently taken this non-prescription medicine.

Pregnancy, breast-feeding and fertility
In the absence of sufficient data, <Product name> should not be used by pregnant or breast-feeding women. The medicinal products potential impact on fertility has not been studied. It is not known if Devil´s claw extract is excreted to breast milk. Safety for the fetus or infant has not been confirmed.

Driving and using machines
In rare cases this product may cause dizziness. If this happens to you, do not drive or use machines.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.
Descriptions of these effects can be found in other sections. Therefore, read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

<Product name> contains lactose
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. How to use <Product name>

Always use this medicine exactly as described in this leaflet or as health care professionals have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is: 1 tablet morning and evening. Should be taken with food and preferably with ½ glass of water. The tablets should be swallowed whole.
You should talk to a doctor if the symptoms worsen or do not improve within 4 weeks.

<Product name> is not recommended for children and adolescents under 18 years of age.

If you use more <Product name> than you should
If you have taken too much of the medicine, or if a child has taken the medicine by accident, always contact a doctor or hospital for risk assessment and advice.

If you forget to take <Product name>
Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Diarrhoea, nausea, vomiting and abdominal pain have been reported, as well as dizziness, headache and allergic skin reactions.

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

5. How to store <Product name>

Do not store above 25ºC.

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 after Exp.date. The expiry date refers to the last day of that month.

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 <Product name> contains

- The active substance is 480 mg extract (as dry extract) of *Harpagophytum procumbens* D.C., radix (Devil´s claw), equivalent to 2.1 – 2.4 g root of Devil´s claw. Extraction solvent: ethanol 60% (V/V).
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, colloidal anhydrous silica, hypromellose, magnesium stearate, talc, titanium dioxide (E171), macrogol (6000), yellow iron oxide (E172) and brown iron oxide (E172).

What <Product name> looks like and contents of the pack

Beige to light-brown oblong tablet
Dimensions:
Length: 19.1 - 19.3 mm
Width: 8.1 - 8.3 mm
Height: 6.0 - 6.2 mm

Pack sizes: 50, 60, 100 and 120 tablets in PVC/PVdC/Al-blisters.
Not all pack sizes may be marketed.

Registration Holder and Manufacturer
<To be completed nationally>

<For any further information about this medicine, please contact the local representative of the Registration Holder:>

<To be completed nationally>

This medicinal product is registered in the Member States of the EEA under the following names:

Denmark: Flexiloges
Finland: Flexiloges
Norway: Flexiloges
Sweden: Flexiloges

This leaflet was last revised in August 1st, 2020.