6.3 Marketing authorisation holder and manufacturer

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Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version. This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.

Package leaflet: Information for the user

Doloteffin®

Film-coated tablets

For use in adults and adolescents

Active substance: Dry extract of devil's claw root

Dear patient!

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Doloteffin® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if your symptoms worsen or you do not feel better.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Doloteffin® is and what it is used for

1.1 Doloteffin® is a herbal remedy for diseases of the locomotor system and the skeletal system.

1.2 Doloteffin® is used for supportive therapy of degenerative diseases of the locomotor system.

In case of acute conditions with e.g., reddening, swelling, or hyperthermia of the joints, as well as with persisting complaints a doctor should be consulted.

2. What you need to known before you take Doloteffin®

2.1 Do not take Doloteffin®

– If you are allergic (hypersensitive) to devil's claw or any of the other ingredients of Doloteffin®.
– With stomach and duodenal ulcers.

2.2 Take special care with Doloteffin®

– In case of gall stone complaints, you should consult a doctor before taking Doloteffin®.

Children:

There is a lack of experience with the use of this drug in children under 12 years of age. Therefore, Doloteffin® shall not be used in children under 12 years of age.

2.3 Taking other medicines

Please tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including medicines obtained without a prescription.

No interactions with other medicines are known.

2.4 Pregnancy and breast-feeding

Due to a lack of experience Doloteffin® should not be taken during pregnancy and breast-feeding periods.

2.5 Ability to drive and to use machines

No special precautions are necessary.

3. How to take Doloteffin®

Always take Doloteffin® exactly as instructed by this leaflet. You should check with your doctor or pharmacist if you are not sure.

3.1 Dosage

In case your doctor did not suggest differently, the usual dose is:

Adults and children over 12 years of age take 2 film-coated tablets 3 times daily.

3.2 Method of administration

For oral use.

Take Doloteffin® film-coated tablets before the meals with plenty of liquid. Avoid to chew the film-coated tablets.

3.3 Duration of administration

Your doctor decides on the duration of administration.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Doloteffin® being too strong or too weak.

3.4 If you take more Doloteffin® than you should

If you accidentally take more Doloteffin® than you should, there are usually no negative consequences. In this case continue taking Doloteffin® as instructed by this leaflet or as your doctor has told you.

3.5 If you forget to take Doloteffin®

Do not take a double dose to make up for a forgotten dose. Continue taking Doloteffin® as instructed by this leaflet or as your doctor has told you.

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

4. Possible side effects

Like all medicines, Doloteffin® can cause side effects, although not everybody gets them.

For the assessment of side effects, the following data on frequency are used as a basis:

Very common:	**More than 1 of 10 patients treated**
Common:	**Less than 1 of 10, but more than 1 of 100 patients treated**
Uncommon:	**Less than 1 of 100, but more than 1 of 1,000 patients treated**
Rare:	**Less than 1 of 1,000, but more than 1 of 10,000 patients treated**
Very rare:	**Less than 1 of 10,000 patients treated, or unknown**

4.1 List of possible side effects

Diarrhoea, nausea, vomiting, bloating, vertigo, and headache may rarely occur.

Hypersensitivity reactions such as skin rash, urticaria, face oedema up to an anaphylactic shock were reported very rarely.

Very rarely, an increase of blood sugar which abated after withdrawal, was observed in insulin-dependent diabetes mellitus.

4.2 If side effects occur, which countermeasures must be taken?

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.

4.3 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 via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-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 Doloteffin®

Keep out of the reach and sight of children.

Do not use this drug after the expiry date which is stated on the carton and on the foils containing the film-coated tablets.

Storage conditions:

Do not store above 25 °C!

6. Further Information

6.1 What Doloteffin® contains

The active substance is:

1 film-coated tablet contains:

Dry extract of devil's claw root (1.5 – 2.5 : 1) 400 mg

Extracting agent: Water

The other ingredients are:

Talc; stearic acid; sodium carboxy-methyl starch; copovidone; colloidal silicon dioxide; maize starch; cellulose powder; macrogol 4000; iron oxides and hydroxides; polyvinyl alcohol; polysorbate 80; titanium dioxide.

For diabetics: Doloteffin® does not contain degradable carbohydrates (no bread exchange, BE).

6.2 What Doloteffin® looks like and contents of the pack

Appearance

Beige-coloured, smooth, shiny, biconvex film-coated tablets.

Packs

Original pack with

20 film-coated tablets

50 film-coated tablets

100 film-coated tablets