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.
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 con-
sequences. 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.

3.6 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:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>More than 1 of 10 patients treated</td>
</tr>
<tr>
<td>Common</td>
<td>Less than 1 of 10, but more than 1 of 100 patients treated</td>
</tr>
<tr>
<td>Uncommon</td>
<td>Less than 1 of 100, but more than 1 of 1,000 patients treated</td>
</tr>
<tr>
<td>Rare</td>
<td>Less than 1 of 1,000, but more than 1 of 10,000 patients treated</td>
</tr>
<tr>
<td>Very rare</td>
<td>Less than 1 of 10,000 patients treated, or unknown</td>
</tr>
</tbody>
</table>

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