

DOLFEIN® Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DOLFEIN

DOLFEIN tablets for oral use contain paracetamol 400 mg, caffeine 50 mg and codeine phosphate hemihydrate 20 mg with the following excipients: microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate, and erythrosine.

DOLFEIN combines codeine phosphate hemihydrate, a centrally acting analgesic, paracetamol, a clinically proven analgesic / antipyretic which produces analgesia by elevation of the pain threshold and caffeine, a central stimulant.

DOLFEIN is indicated for the symptomatic treatment of moderate to severe pain, and in pain not responding to the peripheral analgesics alone.

The way to take DOLFEIN

Take DOLFEIN as directed by your physician.

The recommended dose is one tablet with a full glass of water, repeated if necessary after 4 hours or 2 tablets to be taken in case of severe pain, without exceeding the dose of 6 tablets/day.

In case of severe renal failure (creatinine clearance less than 10 ml/min), the dosing interval should be increased to be at least 8 hours or more.

For elderly and patients with hepatic impairment, the usual dose should be reduced to half; the dosage may be thereafter increased according to the tolerance and the need.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss taking a dose there is no cause for concern, since analgesics may be used only when needed. However, if your health care professional has recommended that you take this drug try to remember to take it as directed. Do not take a double dose at once.

Contraindications

This drug is contra-indicated in the following conditions:

- Hypersensitivity to any of the components
- Liver failure
- Respiratory failure
- Children less than 15 years of age
- Breastfeeding
- Concomitant use of opioids agonist-antagonist (buprenorphine, nalbuphine, pentazocine)
- In patients who are known as rapid metabolizers of CYP2D6 substrates.

Precautions

- Prolonged use of large doses of codeine may lead to dependence.
- Neurogenic pain by deafferentation does not respond to paracetamol-codeine combination.
- In cholecystectomized patients, codeine can cause acute abdominal pain syndrome of biliary or pancreatic type.
- In case of intracranial hypertension, codeine may increase the importance of this hypertension.
- Consult your doctor before using this medication in case of pregnancy.
- Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use with opioids agonist-antagonist (buprenorphine, nalbuphine, pentazocine) is contra-indicated.

Concomitant use with alcohol or medicines containing alcohol is not recommended.

Use caution with other narcotic (analgesics, antitussives, and substitution treatment), barbiturates, benzodiazepines, neuroleptics, anxiolytics, sedative antidepressants (amitriptyline, doxepine, mianserine, mirtazapine, trimipramine), sedative antihistamines, central antihypertensive, baclofen, pizotifen, and thalidomide.

Adverse reactions

Reported adverse reactions include: constipation, nausea, vomiting, drowsiness, dizziness, bronchospasm, respiratory depression, abdominal pain syndrome of biliary or pancreatic type, excitation, insomnia, and palpitations.

Hypersensitivity reactions and thrombocytopenia have been rarely reported.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

DOLFEIN, pack of 30 tablets

Issue date: 01/2016

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