

Package Leaflet: Information for the patient

Feminax Tablets

Paracetamol 500 mg, Codeine Phosphate 8 mg,
Hyoscine Hydrobromide 100 micrograms, Caffeine (as monohydrate) 50 mg

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 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 3 days.

What is in this leaflet:

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

1. What Feminax Tablets are and what they are used for

Feminax Tablets rapidly relieve period pain. They relieve the cramping pain and backache you experience with period pain.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

Hyoscine hydrobromide is a drug that relaxes smooth muscle and may relieve spasms.

2. What you need to know before you take Feminax Tablets

Do not take Feminax Tablets:

- if you are allergic to paracetamol, codeine, hyoscine or caffeine or any of the other ingredients of this medicine (listed in section 6)
- if you have recently drunk alcohol
- if you suffer from glaucoma (raised pressure in the eyes)
- if you have asthma or severe breathing problems
- if you have a head injury or raised pressure in the brain
- if you have severe liver problems including those caused by alcoholic liver disease
- if you know that you metabolise very rapidly codeine into morphine
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to the obstructive sleep apnoea syndrome
- if you are breastfeeding

Not to be taken by children under the age of 12.

Warnings and precautions

Talk to your doctor or pharmacist before taking Feminax Tablets:

- if you have liver, kidney, heart, gastrointestinal or metabolic problems
- if you have diabetes mellitus, have difficulty passing water or suffer from seizures or fits
- if you have glucose-6-phosphate dehydrogenase deficiency (a hereditary condition that may result in anaemia) or have yellowing of the skin or whites of the eyes caused by liver or blood problems
- if you are breastfeeding.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Do not take with any other paracetamol containing product.

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in children.

Other medicines and Feminax Tablets

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

Please tell your doctor or pharmacist if you:

- Are taking medicines containing codeine, paracetamol, metoclopramide or domperidone (used to treat nausea and vomiting), colestyramine (used to treat high cholesterol), or propantheline (used to treat cramps or spasms)
- Are taking medicines to treat epilepsy (e.g. phenytoin, carbamazepine or phenobarbital)
- Are taking medicine to help you sleep or any other medication that makes you drowsy (e.g. glutethimide)
- Are taking amantadine (an antiviral), antihistamines, antipsychotics or antidepressants
- Are taking zidovudine (used to treat HIV infection)
- Are taking rifampicin or chloramphenicol (antibiotics)
- Are taking tropisetron and granisetron (used to treat nausea and vomiting)
- Are taking medicine to thin your blood e.g. warfarin

This product contains codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor. Taking a painkiller for headaches too often or for too long can make them worse.

Feminax Tablets with food, drink and alcohol

Do not drink alcohol while taking Feminax tablets.

Pregnancy

Medicines containing codeine may be taken sparingly during pregnancy upon advice of a doctor when the potential benefits outweigh the risks. However, there is a risk of breathing problems in the newborn if large doses are taken before delivery, and there is a risk of withdrawal symptoms in the newborn in the event of regular use by the mother at the end of pregnancy.

Breast-feeding

Do not take codeine while you are breastfeeding. Codeine and morphine pass into breast milk.

Driving and using machines:

May cause drowsiness. If affected do not drive or operate machinery.

3. How to take Feminax Tablets

Always take Feminax Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12: take up to 2 tablets at the first onset of symptoms; then if necessary up to 2 tablets every 4 hours. Do not take more than 6 tablets in 24 hours. Do not exceed the stated dose.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Feminax Tablets should not be taken by children below the age of 12 years.

If you take more Feminax Tablets than you should: Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

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

If you forget to take Feminax Tablets: Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, they can have side effects, although not everybody gets them. Most people taking Feminax tablets find they cause no problems.

Feminax tablets may cause drowsiness. If affected do not drive or operate machinery.

Allergic reactions including skin rash, anaphylactic reaction and anaphylactic shock may occur.

Very rare cases of serious skin reactions have been reported.

Occasionally, the following side effects may occur:

constipation, nausea, vomiting, stomach discomfort, abdominal pain, diarrhoea, dizziness, light-headedness, confusion, drowsiness, restlessness, hallucination, tremors, dry-mouth, flushing, skin disorders including Stevens-Johnson syndrome, rash, itching, hives, fluid retention, sedation, blurred vision, dilated pupils, irregular heartbeat or awareness of your heartbeat, shortness of breath, liver disorders including hepatitis and liver impairment, changes in the number of blood cells may occur, which might mean you bleed or bruise more easily and infection may be more likely.

The prolonged use of high doses of Feminax may lead to liver and kidney damage.

In cases of alcohol abuse, taking paracetamol, even at the recommended dose, may result in liver damage.

These effects should go away once you stop taking Feminax Tablets.

Hearing loss has been reported for paracetamol and codeine combination products following prolonged use at higher than recommended doses.

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Feminax Tablets

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

Do not store above 25°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 Feminax Tablets contains

Each tablet contains the active ingredients paracetamol 500 mg, codeine phosphate 8 mg, caffeine monohydrate equivalent to 50 mg anhydrous caffeine, hyoscine hydrobromide 100 micrograms.

The other ingredients are sodium starch glycolate, purified talc, gelatin powder, stearic acid, sodium lauryl sulfate.

What Feminax Tablets look like and the contents of the pack

Feminax Tablets are white oval, tablets, with a score line on one side. The other side is engraved with 'Feminax'.

They are available in a pack size of 20 tablets.

Marketing Authorisation Holder

Bayer Limited, The Atrium, Blackthorn Road, Dublin 18.

Manufacturer

Pharmapac UK. Ltd, Bidston, Wirral CH41 7EL U.K.

This leaflet was last approved in November 2015.