

PACKAGE LEAFLET: INFORMATION FOR THE USER

DF118 FORTE 40mg Tablet

Dihydrocodeine Tartrate

Read all of this leaflet carefully before you use DF118 FORTE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you must not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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2. Before you take DF118 FORTE
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1. What DF118 FORTE is and what it is used for

Dihydrocodeine is an alkaloid with powerful pain relieving properties. This medicine is used for the relief of severe and long-lasting pain.

2. Before you take DF118 FORTE

You should not take DF118 FORTE if:

- you are allergic (hypersensitive) to Dihydrocodeine or any of the ingredients of this medicine (listed in section 6 and 'Important information about some of the ingredients, column 2).
- you are taking or have recently taken any drugs used to treat depression known as Monoamine Oxidase Inhibitors (MAOI)s (see 'Taking other medicines')
- you suffer from breathing difficulties, for example acute asthma attacks
- you are suffering from severe headaches or have suffered a head injury
- you suffer from alcoholism
- you suffer from heart problems after a lung disease
- you are suffering from stomach pains
- you are suffering from a problem that could cause paralysis of the small intestine (paralytic ileus)
- you have a tumour of the adrenal gland known as pheochromocytoma

Take special care with DF118 FORTE

Tell your doctor if:

- you suffer from asthma
- you have an underactive thyroid gland
- you suffer from low blood pressure
- you have liver or kidney problems
- you suffer from a convulsive disorder (fits) such as epilepsy
- you have any prostate problems
- you have any breathing or lung problems or a productive cough

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without prescription.

DF118 FORTE **must not** be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as Monoamine Oxidase Inhibitors (MAOI's).

Other medicines which may interact with DF118 FORTE include:

- medicines for sleeping problems and anxiety, such as chloral, diazepam, and barbiturates.
- CNS depressants (drugs that act on the brain to cause drowsiness)
- ciprofloxacin, a drug used to prevent and treat bacterial infections
- alcohol

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Taking DF118 FORTE with food and drink

DF118 FORTE should be taken with or after food. You are advised not to drink alcohol while being treated with Dihydrocodeine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or you are breast-feeding, you should consult your doctor before taking DF118 FORTE.

Driving and using machines

This medicine can affect your ability to drive and operate machinery. Do not drive or operate machinery if you feel drowsy or cannot think clearly.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

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talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients

If you have been told by your doctor that you have an intolerance to some sugars (lactose), contact your doctor before taking this medicinal product.

3. How to take DF118 FORTE

Your doctor will decide on the dose and duration of your therapy.

Always follow the instructions of your doctor and pharmacist.

This medicine is for oral use.

Adults and elderly: One or two tablets three times daily taken with or after food up to a maximum of 6 tablets per day.

Children under 12 years: Not recommended.

If you forget to take DF118 FORTE

If you have missed a dose take it as soon as you remember unless it is nearly time for your next dose. Then continue your normal dose times. Do not take a double dose.

If you take more DF118 FORTE than you should

If you take too much of your medicine seek **immediate** medical advice from your doctor or your nearest hospital. Symptoms of an overdose include sudden or unexpected difficulty in breathing, pin-point pupils or a drop in blood pressure. In the case of children they may suffer fits.

4. Possible side effects

Like all medicines, DF118 FORTE can cause side effects, although not everybody gets them.

Repeated use of Dihydrocodeine can result in tolerance and addiction.

If you experience any of the following side effects stop taking the tablets and contact your doctor or go to the casualty/emergency department of your nearest hospital **immediately**. These are symptoms of an allergic reaction.

- difficulty in breathing with or without swelling of the face, lips, tongue and/or throat
- swelling of the face, lips tongue and/or throat, which may cause difficulty in swallowing
- severe itching of the skin (with raised lumps).

Other side effects that may occur include:

- hallucinations (seeing or hearing things that aren't real)
- confusion
- changes in mood
- feeling of being unwell
- headaches
- dizziness or a feeling of spinning (vertigo)
- drowsiness
- sweating
- feeling faint when getting up from a seated position

- pin-point pupils
- fast, slow or irregular heartbeat
- facial flushing
- difficulty breathing
- constipation
- feeling sick (nausea)
- being sick (vomiting)
- dry mouth
- difficulty passing urine
- lower abdomen spasms
- an itchy rash or redness
- decrease in sex drive or ability to achieve and maintain an erection
- lower body temperature
- serious allergic reaction (anaphylaxis)

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• lower body temperature

• serious allergic reaction (anaphylaxis)

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. Storing DF118 FORTE

Keep all medicines out of the sight and reach of children.

Do not use DF118 FORTE after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C in a dry place. Protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What DF118 FORTE contains:

Active ingredients: Dihydrocodeine Tartrate 40 mg per tablet

Other ingredients: lactose, maize starch, pregelatinised maize starch and magnesium stearate.

What DF118 FORTE looks like and contents of the pack:

DF118 FORTE is a white, circular tablet supplied either in a plastic container or in plastic blister packs. Each pack contains 10, 28, 56, 100 or 500 tablets.

Marketing Authorisation

Holder: Martindale Pharmaceuticals Ltd
Bampton Road
Romford Essex RM3 8UG, UK

Manufacturer:

Dales Pharmaceuticals Ltd
Snaygill Industrial Estate
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