

**DF118 FORTE 40mg Tablet**

## Dihydrocodeine Tartrate

**This medicine contains dihydrocodeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**Read all of this leaflet carefully before you start using DF118 FORTE because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What DF118 FORTE is and what it is used for
2. What you need to know before you take DF118 FORTE
3. How to take DF118 FORTE
4. Possible side effects
5. How to store DF118 FORTE
6. Contents of the pack and other information

**1. What DF118 FORTE is and what it is used for**

This medicine has been prescribed for you for the relief of severe and long lasting pain including the pain of sciatica (nerve pain of the leg/back), joint and bone pain (osteoarthritis, rheumatoid arthritis of the spine), nerve pain, pain following blood vessel disease, cancer or after operations.

It contains dihydrocodeine which belongs to a class of medicines called opioids, which are pain relievers. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

**2. What you need to know before you take DF118 FORTE****Do 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 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 are suffering from a problem that could cause paralysis of the small intestine (paralytic ileus)

**Warning and Precautions**

Talk to your prescriber before taking DF118 FORTE:

- if you suffer from asthma
- if you have an underactive thyroid gland
- if you suffer from low blood pressure or are in shock
- if you have liver or kidney problems
- if you have a convulsive disorder (fits) such as epilepsy
- if you have an enlarged prostate glands and have difficulty urinating
- if you have any breathing or lung problems or a productive cough
- if you have suffered with allergies
- if you are weak due to illness
- if you have adrenal gland insufficiency (symptoms include low blood pressure, low blood sugar, muscle weakness, nausea, vomiting, dizziness, skin discolouration, weight loss)
- if you have a convulsive disorder (suffer from spasms/seizures)
- if you have inflammation or blockage in the bowel (symptoms may include constipation, diarrhoea, abdominal pain/discomfort)
- if you have a history of drug abuse.
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or

sweating, when you have stopped taking alcohol or drugs.

- you feel you need to take more of DF118 FORTE to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

**Other medicines and DF118 FORTE**

Please tell your doctor or pharmacist if you are taking or have recently taken or might take 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 e.g. amitriptyline (drugs that act on the brain to cause drowsiness)
- ciprofloxacin, a drug used to prevent and treat bacterial infections
- alcohol
- treating allergies (antihistamines)
- used to treat sickness (cyclizine, metoclopramide or domperidone)
- treating mental illnesses e.g. chlorpromazine, haloperidol
- such as mexiletine used to control heart rhythm
- such as cimetidine (to treat stomach ulcers)
- used in anaesthesia (important if you have recently or are about to receive treatment where an anaesthetic may be used)

Concomitant use of Dihydrocodeine Tartrate 40mg Tablets and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Dihydrocodeine Tartrate 40mg Tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

**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, breast-feeding and fertility**

Do not take DF118 FORTE if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits

of treatment are considered to outweigh the potential harm to the baby.

If you use DF118 FORTE during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take DF118 FORTE while you are breastfeeding as dihydrocodeine passes into breast milk and will affect your baby.

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

**DF118 FORTE contains Lactose**

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 prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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

**This medicine is for oral use.**

**Adults and elderly and children over 12 years:** 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 to make up for a forgotten 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.

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

**If you stop taking DF118 FORTE**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

**4. Possible side effects**

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

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.

- **Gastrointestinal system** – constipation, feeling or being sick, abdominal pain, dry mouth
- **Nervous system** – ‘spinning’ sensation, dizziness, headache, ‘pins and needles’, slow and shallow breathing, muscle rigidity.
- **Skin** – rash, itchy skin, irregular raised patches, sweating, flushed face

- **Eyes** – blurred or double vision, extremely small pupils

- **Psychiatric effects** – drowsiness, changes of mood, confusion, sexual dysfunction, hallucinations (seeing or hearing things that are not real), excitement, frequency unknown: dependence and addiction (see section ‘How do I know if I am addicted?’)

- **Heart** – slow or fast heart rate, palpitations, low blood pressure

- **Liver and biliary system** – biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- **Urinary system** – pain and difficulty in passing urine and less frequent to do so
- **Other** – water retention (oedema)

**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.**

**Drug Withdrawal**

When you stop taking DF118 FORTE, you may experience withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

**How do I know if I am addicted?**

If you notice any of the following signs whilst taking DF118 FORTE, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store 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. Contents of the pack and other Information****What DF118 FORTE contains:**

**Active ingredient:** 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:**

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**Manufacturer:**

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