Package Leaflet: Information for the patient

DHC® Continus® 60 mg, 90 mg and 120 mg prolonged-release tablets
Dihydrocodeine tartrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What DHC Continus tablets are and what they are used for
2. What you need to know before you take DHC Continus tablets
3. How to take DHC Continus tablets
4. Possible side effects
5. How to store DHC Continus tablets
6. Contents of the pack and other information

1. What DHC Continus tablets are and what they are used for

These tablets have been prescribed for you to relieve severe pain over a period of 12 hours. They contain the active ingredient dihydrocodeine which belongs to a group of medicines called strong analgesics or ‘painkillers’.

The tablets may be taken by adults and children aged 12 years and above.

2. What you need to know before you take DHC Continus tablets

Do not take DHC Continus tablets if you:
- are allergic to dihydrocodeine or any of the other ingredients of the tablets (listed in section 6);
- have severe breathing problems such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- are having an asthma attack;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus);
- are addicted to alcohol;
- have an intolerance to some sugars;
- are under 12 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking these tablets if you:
- are elderly;
- have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the tablets may make these symptoms worse or hide the extent of a head injury;
- have breathing problems such as chronic obstructive lung disease, bronchial asthma or respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have an under-active thyroid gland (hypothyroidism);
- have severe kidney problems;
- have liver problems;
• have constipation or obstructive bowel disorders;
• have inflammation of the pancreas (which causes severe pain in the abdomen and back);
• have problems with your gall bladder or bile duct;
• have an enlarged prostate gland, which causes difficulty in passing urine (in men);
• have a heart problem after long-term lung disease (cor pulmonale);
• are or have ever been addicted to alcohol or drugs or have a known opioid dependence;
• need to take increasingly higher doses of the tablets to gain the same level of pain relief (tolerance).

You may experience hormonal changes while taking these capsules. Your doctor may want to monitor these changes.

Other medicines and DHC Continus tablets
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking:
• medicines to help you sleep (for example benzodiazepines, tranquillisers, hypnotics or sedatives);
• medicines to treat psychiatric or mental disorders (such as phenothiazines);
• medicines to treat anxiety;
• a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks.

Concomitant use of opioids and benzodiazepines 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 benzodiazepines or related drugs with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

Please follow your doctor’s dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

DHC Continus tablets and alcohol
Drinking alcohol during your treatment with these tablets may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking these tablets.

Newborn babies may suffer withdrawal effects (such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea) if their mothers have taken dihydrocodeine for a long time during pregnancy.

If you are breastfeeding, do not take these tablets until you have spoken to your doctor.

Driving and using machines
These tablets may cause a number of side effects such as drowsiness, which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the tablets or when changing to a higher dose. If you are affected you should not drive or use machinery.

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 while you have this medicine in your body over a specified limit unless you have a defence (called the ‘statutory defence’).
• This defence applies when:
  • 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 and in the information provided with the medicine.
• Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law.

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

**DHC Continus tablets contain lactose**
These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. **How to take DHC Continus tablets**

Always take these tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often. Do not take for longer than directed by your doctor. Check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with a glass of water. **Do not break, chew or crush them.**

**DHC Continus tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o’clock in the morning, you should take your next tablet at 8 o’clock in the evening.

**Adults and children over 12 years of age**
The usual starting dose is 60 mg to 120 mg every 12 hours. If you are elderly your doctor may suggest a lower starting dose. Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor.

**Use in children**
Children under 12 years of age should not take the tablets.

**If you take more DHC Continus tablets than you should or if someone accidentally swallows your tablets**
Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show the doctor.

**If you forget to take DHC Continus tablets**
If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking DHC Continus tablets**
You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. Withdrawal symptoms such as agitation, anxiety, shaking or sweating may occur if you suddenly stop taking these tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. **Possible side effects**

Like all medicines, these tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are uncommon. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face, lips or throat, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you.

As with all strong painkillers, there is a risk you may become addicted or reliant on these tablets.

Taking a painkiller for headaches too often or for too long can make your headaches worse.

**Common side effects** (May affect more than 1 in 100 people)
- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days).
- Dry mouth, abdominal pain or discomfort.

**Uncommon side effects** (May affect fewer than 1 in 100 people)
- Diarrhoea, a condition where the bowel does not work properly (paralytic ileus).
- Mood changes, unpleasant or uncomfortable mood.
- Headache, confusion, a feeling of unusual weakness, tiredness, generally feeling unwell.
- Hallucinations.
- Blurred vision.
- A feeling of dizziness or 'spinning', seizures, fits or convulsions.
- Tingling or numbness.
- Low blood pressure.
- Decreased sexual drive.
- Difficulty in passing urine.
- Flushing of the skin.
- Rash or itchy skin.
- Shortness of breath.
- Sweating.
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance).
- A worsening in liver function tests (seen in a blood test).

**Side effects with unknown frequency** (frequency cannot be estimated from the available date)
- Withdrawal symptoms in babies born to mothers who have used **DHC Continus** tablets in pregnancy (see “Pregnancy and breastfeeding” in section 2).

**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 the Yellow Card Scheme at: 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 DHC Continus tablets**

Keep these tablets out of the sight and reach of children.
Do not use the tablets after the expiry date, which is stated on the carton and blister after ‘EXP’. The expiry date refers to the last day of that month e.g. EXP 08 2020 means that you should not take the tablets after the last day of August 2020.

Do not store your tablets 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 DHC Continus tablets contain
The active ingredient is dihydrocodeine tartrate. Each tablet contains 60 mg, 90 mg or 120 mg of dihydrocodeine tartrate.

The other ingredients are:
• Lactose
• Hydroxyethylcellulose
• Cetostearyl alcohol
• Magnesium stearate
• Talc

What DHC Continus tablets look like and the contents of the pack
The tablets are white, capsule shaped and marked DHC followed by the strength (e.g. 60, 90 etc.).

In each bottle there are 56 tablets.

Marketing Authorisation Holder and Manufacturer
The tablets are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.
This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line (free of charge) on:

0800 198 5000

You will need to give details of the product name and reference number. These are as follows:

Product name: DHC Continus prolonged-release tablets
Reference number: 16950/0019

This leaflet was last revised in February 2018

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