1st fold (26.25cms)

2nd PDF sent on - 27TH APRIL 2015

2nd fold (28.25cm)

3rd fold (26.25cms)

3rd PDF sent on - 6TH APRIL 2015

4th fold (26.25cms)

ARTWORK (DETAILS)

PRODUCT : Codeine Phosphate Tablets

FILE NAME : 270428F01-220891-L1

DIMENSIONS : 220891

CHANGE CONTROL :
Version changes due to change in:
• Removed pre-printed India neutral code
• Added arrow to indicate pharmacode reading
• Pharmcode placed on 8mm from the cutting edge

ARTWORK CHECK BOX

pg 1/2
3. HOW CODEINE PHOSPHATE TABLETS SHOULD BE GIVEN

The usual starting dose for adults and children aged 12 years or above for relief of minor to moderate pain is 30mg to 60mg every 4 hours, as needed. The usual adult starting dose for diarrhoea is 30mg, three or four times daily. No more than 240mg should be taken in 24 hours. In all cases, dosage will be reduced for elderly. Codeine Phosphate tablets should not be taken by children under 12 years due to the risk of severe breathing problems. Codeine Phosphate Tablets are not recommended for the treatment of diarrhoea in children. You may need a reduced dose if you have kidney or liver problems. You may also be given a reduced dose if you suffer from any of the conditions listed above in the section headed ‘Speak to your doctor before you take Codeine Phosphate Tablets’.

Always follow your doctor’s instructions completely. Also, follow any special instructions or warnings that appear on the label that the pharmacist has put on the package. If you do not understand or are in any doubt, ask your pharmacist.

Unless instructed differently, take your tablets with a glass of water. If you have been given a blister pack, to obtain a tablet, press on the tablet from the blister (or bubble) pushing it through the foil. Do not remove the tablet from the blister until you are ready to take it.

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.

If you miss a dose of Codeine Phosphate Tablets

You should continue to take your medicine for as long as your doctor tells you to. If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER double the next dose to make up for the one missed. Do not stop taking the medicine without telling your doctor first.

If treatment with Codeine Phosphate Tablets is stopped

You should always check with your doctor before the treatment is stopped. It is possible that you could become dependent on codeine and have withdrawal symptoms if it is stopped suddenly. This is more likely if you have a tendency for drug abuse or if you become dependent on Codeine Phosphate Tablets.

4. POSSIBLE SIDE EFFECTS

Like all medicines, codeine can cause side effects, but not everybody gets them. Tell your doctor or nurse immediately if you experience the following serious side effect:

• a severe allergic reaction (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing). If you suffer such a reaction, you should not be given any more codeine. Your doctor will decide on the appropriate treatment for allergic reactions. Difficulty in breathing and physical and psychological dependence are possible serious side effects. It is possible that you could become dependent on codeine.

Side effects that are common include:

• headache
• feeling sick or being sick
• constipation
• diarrhoea

Apart from constipation, these side effects tend to disappear with time. Side effects that are less common include:

• dizziness
• feeling faint or standing up
• small pupils (in the eye)
• blurred vision
• double vision or other changes in vision
• mental clouding or confusion
• mood changes such as depression and sadness
• feeling extremely happy for no particular reason
• imagining things (hallucinations)
• nightmares
• anxiety
• restlessness
• vertigo
• palpitations (racing, irregular heart beats)
• anxiety
• feeling fatigued
• hypotension
• fever
• an enlarged spleen or swollen/enlarged lymph nodes
• anorexia
• uncontrollable muscle movements
• numbness
• muscle rigidity
• slower or faster pulse
• skin rash
• wheals or itching
• reduced sexual drive or impotence after long term use

Reporting of side effects

If you get any side effects, ask the doctor, pharmacist or nurse. If you feel that any of the possible side effects you are experiencing concern you, tell your doctor or nurse immediately.

5. HOW TO STORE CODEINE PHOSPHATE TABLETS

Do not store above 25°C. Store in the original package or container in which they were given to you in order to protect from light. Do not transfer them to another container.

Keep out of the reach and sight of children.

Do not use Codeine Phosphate Tablets if the tablets show signs of discolouration. Do not use Codeine Phosphate Tablets after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

REMEMBER this medicine is for YOU only. Never give it to anyone else. It may harm them, even if the symptoms are the same as yours. Unless your doctor tells you to, do not keep tablets that you no longer need. Give them back to the pharmacist.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

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<th>Reference number</th>
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<tr>
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<tr>
<td>Codeine Phosphate 30mg Tablets</td>
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<tr>
<td>Codeine Phosphate 60mg Tablets</td>
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