139.7 mm

12 mm | 115.7 mm | 12 mm

228.6 mm

208.6 mm

10 mm

Direction of travel past pharmacode scanner

First bar 2mm 8mm

40 mm lead-in

PATIENT INFORMATION LEAFLET

Veganin Tablets

Paracetamol 500 mg; Caffeine 30 mg; Codeine Phosphate 8 mg

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Veganin carefully to get the best results from it.

This medicine can only be used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.

You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice.

This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.

If you take this medicine for headaches for more than three days it can make them worse.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist straightaway.

In this leaflet:

1. What Veganin is and what it is used for
2. Before you take Veganin
3. How to take Veganin
4. Possible side effects
5. Storing Veganin
6. Further information

1. What Veganin is and what it is used for

Veganin can be used in patients over 12 years of age for the short term relief of moderate pain that is not relieved by other painkillers such as paracetamol, or ibuprofen alone. It is suitable for the treatment of migraine, headache, rheumatic pain, period pain, toothache and neuralgia.

Veganin is a tablet containing paracetamol, caffeine and codeine phosphate. Paracetamol and codeine are painkillers. 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. Paracetamol also helps lower a high temperature and acts as a mild anti-inflammatory, to reduce swelling.

Caffeine is a mild stimulant that causes wakefulness and increased mental activity. It can also help the effectiveness of paracetamol.

2. Before you take Veganin

This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.
If you take a pain killer for headaches for more than three days it can make them worse.

Do not use this medicine:

- if you are allergic (hypersensitive) to any of the ingredients of Veganin (see section 6)
- if you have asthma or very shallow breathing
- if you suffer from alcoholism
- if you have a head injury or increased pressure in your skull
- if you have had surgery on your bile duct
- if you are already taking a medicine containing paracetamol
- for a child younger than 12 years old
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you know that you metabolise very rapidly codeine into morphine
- if you are breastfeeding.

Take special care with Veganin

Tell your doctor or pharmacist if:

- you have severe liver or kidney problems. The risk of overdose is higher if you have alcoholic liver disease
- you are elderly because you may be more likely to get some side effects (see section 4)
- you have prostate problems
- you have bowel problems, particularly those causing inflammation or blockage, or you have had recent bowel surgery. If you have any of these conditions, your doctor or pharmacist will advise you about how best to use Veganin.

Taking other medicines

Before using Veganin, tell your doctor or pharmacist if you are taking any of the following:

- metoclopramide or domperidone - used to treat nausea and vomiting
- colestyramine - used to treat high cholesterol
- anti-coagulants (such as warfarin) - used to thin the blood. It is alright to take occasional doses of Veganin, but not if Veganin is required daily over a long period
- sedatives (also known as sleeping tablets) containing barbiturates
- certain medicines prescribed for depression (called MAOIs) or have been taking them in the last 2 weeks
- medicines for diarrhoea and tummy cramps as taking these at the same time as Veganin may make you constipated
- medicines such as atropine, procyclidene or hyoscine which are used to treat problems with gut movements. Taking these at the same time as Veganin may make you severely constipated and may make it difficult for you to pass urine
- some antihistamines which may be used in cough/cold remedies and anti-allergy products. Taking these at the same time as Veganin may make you severely constipated and may make it difficult for you to pass urine
- quinidine or mexiletine - used to regulate heart rhythm
- cimetidine - used to treat stomach ulcers
- naltrexone - used in the treatment of drug dependence.

If you are taking any of the following medicines, you may find the effectiveness of Veganin is reduced:

- oral contraceptives ('the pill')
- medicines used to treat epilepsy (anticonvulsants).

If you are unsure if any medicine you are taking is one of those mentioned above, check with your pharmacist.

Alcohol
Do not drink alcohol while taking Veganin as it can make liver damage and breathing difficulties more likely and more serious.

Warnings and precautions
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.

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 these children.

Pregnancy and breast feeding
Ask your doctor or pharmacist for advice before taking Veganin if you are pregnant. Do not take Veganin while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines
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 taken to treat a medical or dental problem and
  - You have taken it according to 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.

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

3. How to take Veganin

Do not exceed the stated dose.
Adults, elderly and children over 12 years: Swallow two tablets with water every 4-6 hours.

Do not take more than 8 tablets in 24 hours. If you have already taken another painkiller wait at least four hours before taking Veganin.

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.

Veganin should not be taken by children below the age of 12 years, due to the risk of severe breathing problems. Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Special warnings about addiction: This medicine contains codeine and can **cause addiction** if you take it continuously for more than three days. When you **stop taking** it you may get **withdrawal symptoms.** You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional.

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**

By reporting side effects you can help provide more information on the safety of this medicine.
If you get any of the following side-effects, **you must stop taking Veganin and get medical help straight away:**

- sweating, red face, allergic reactions such as a skin rash, itchy skin or swelling of the face. These may be the symptoms of a severe allergic reaction.

These side-effects are less serious. If they bother you talk to a pharmacist or your doctor:

- drowsiness, dizziness, headache, vertigo (a sense of spinning either of yourself or your surroundings), nervousness, irritability, blurred or double vision
- stomach cramps, constipation, feeling sick (nausea), being sick (vomiting), dry mouth
- difficulty or pain in urinating, needing to pass urine more often, or passing less urine than usual
- palpitations (awareness of your heart beat)
- low blood pressure (often feeling faint or dizzy upon standing up). Rare: reports of blood disorders including low platelet count (making you slow to heal and bruise easily) and low white blood cell count (making you more likely to get infections)
- becoming used to the effects of Veganin (the same dose does not seem to work so well) and becoming dependent or addicted, especially with prolonged use
- seeing, hearing or feeling things that are not real (hallucinations), nightmares and restlessness. These are rare.

How do I know if I am addicted?
If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- you need to take the medicine for longer periods of time
- you need to take more than the recommended dose
- when you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again.

5. Storing Veganin

Do not store above 25°C. Keep the tablets in the original packaging. Keep out the reach and sight of children.

Do not use Veganin after the date (month and year) printed after "EXP" on the box and blister strip. If the expiry date has passed, take the product back to your pharmacist for safe disposal.

6. Further information

What Veganin contains
The active substances are:
Paracetamol 500 mg, Codeine phosphate 8 mg and Caffeine 30 mg in each tablet.

The other ingredients:
Maize starch, methylcellulose, povidone, talc, calcium stearate, hypromellose, polyethylene glycol and water.

What Veganin looks like and contents of pack
Veganin are white capsule shaped film-coated tablets supplied in a blister strip in a carton.
There are 10 or 30 tablets in a pack.

Marketing Authorisation holder
Omega Pharma Ltd., 1st Floor, 32 Vauxhall Bridge Road, London, SW1V 2SA, United Kingdom.
Send all enquiries to this address.

Manufacturer
Wrafton Laboratories Ltd, Wrafton, Braunton, North Devon, EX33 2DL.

This medicinal product is authorised in the Member States of the EEA under the following names:
United Kingdom: Veganin Tablets
Republic of Ireland: Veganin Plus Tablets

Text revised: April 2014

2539957

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Direction of travel past pharmacode scanner

First bar 2mm 8mm

40 mm lead-in

3 mm | 1 mm | 11 mm

Same dimensions on all corner eye marks