

PATIENT INFORMATION LEAFLET: Information for the user

Veganin Plus Tablets

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

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.
- Ask your pharmacist if you need more information or advice.
- 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.

This medicine is available without prescription. However, you still need to use Veganin Plus 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.

What is in this leaflet

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

1. What Veganin Plus is and what it is used for

Veganin Plus 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 Plus is a tablet containing paracetamol, caffeine and codeine phosphate. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol is another analgesic to relieve pain. Caffeine is a mild stimulant that causes wakefulness and increased mental activity.

2. What you need to know before you take Veganin Plus

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.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

If you take a pain killer for headaches for more than three days it can make them worse.

Do not take Veganin Plus:

- if you are allergic (hypersensitive) to any of the ingredients of Veganin Plus (see section 6)
- if you have asthma or very shallow breathing
- if you suffer from alcoholism
- If you experience or have had the type of chronic constipation called paralytic ileus
- 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.

Warnings and precautions

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 had your gall bladder removed
- 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 Plus.

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.

Other medicines and Veganin Plus

Before using Veganin Plus, 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 Plus, but not if Veganin Plus 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
- decongestants (e.g. pseudoephedrine or ephedrine, found in some cough and cold remedies)
- sedatives and tranquilisers, such as benzodiazepine and non-benzodiazepine hypnotics
- medicines for diarrhoea and tummy cramps as taking these at the same time as Veganin Plus 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 Plus 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 Plus 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.

Please inform your doctor or pharmacist if you are taking:

-flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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

- oral contraceptives ('the pill')
- medicines used to treat epilepsy, such as carbamazepine, fosphenytoin, phenytoin or phenobarbital.

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

Veganin Plus and food and drink

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

Veganin Plus and alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Veganin Plus while you are breast-feeding. 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 prescribed to treat a medical or dental problem
 - 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.

3. How to take Veganin Plus

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

Adults, including the elderly: 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 Plus.

Children aged 16 – 18 years: Swallow one to two tablets with water every 6 hours, when necessary. Do not take more than 8 tablets in 24 hours.

Children aged 12 – 15 years: Swallow one tablet with water every 6 hours, when necessary. Do not take more than 4 tablets in 24 hours.

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 Plus should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Veganin Plus than you should

Talk to your 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.

If you forget to take Veganin Plus

Do not take a double dose to make up for a forgotten dose.

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

If you stop taking Veganin Plus

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. If you take medicine according to the instructions on the pack, it is unlikely that you will become addicted to the medicine.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side-effects you should know about Veganin Plus:

- taking a painkiller for headaches too often or for too long can make them worse
- taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets

If you get any of the following side effects, you must stop taking Veganin Plus 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
- 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)

If you get any of these side effects, stop taking the medicine and seek medical advice as soon as possible:

- difficulty in breathing (if you are sensitive to aspirin or other NSAIDs)
- liver dysfunction
- serious skin reactions (very rare cases have been reported)
- cloudy urine
- 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)
- inflammation of the pancreas if you have had your gall bladder removed

Talk to a pharmacist or your doctor if you experience any of the below side effects:

- drowsiness, dizziness, headache, vertigo (a sense of spinning either of yourself or your surroundings)
- blurred or double vision, facial flushing
- constipation, feeling sick (nausea), being sick (vomiting), heartburn, dry mouth
- stomach cramps
- seeing hearing or feeling things that are not real (hallucinations), nightmares and restlessness
- shiver
- nervousness, irritability

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 HPRA Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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. How to store Veganin Plus

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Keep the tablets in the original packaging.

Do not use this medicine after the expiry date which is stated on the carton and blister strip after "EXP". The expiry date refers to the last day of that month.

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 Veganin Plus 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 Plus looks like and contents of pack

Veganin Plus 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:

Chefaro Ireland DAC

The Sharp Building

Hogan Place

Dublin 2

Ireland

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

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