

PATIENT INFORMATION LEAFLET: Information for the user

Veganin Plus Tablets Paracetamol 500 mg; Caffeine 30 mg; Codeine Phosphate Hemihydrate 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.
- You must contact your doctor if your symptoms worsen or do not improve after 3 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 this medicine
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.

This product should be used only when clearly necessary.

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.

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.

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

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

Do not take **Veganin Plus:**

- if you are allergic to paracetamol, codeine, caffeine, or any of the other ingredients of this medicine (listed in section 6); if you suffer from acute asthma (if you have suffered from recent asthma attacks) 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 recently had gall bladder surgery or a similar operation
- if you have had surgery on your bile duct
- if you are already taking a medicine containing paracetamol
- if you are under 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.
- if you suffer from chronic constipation.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

- if you suffer from an enlarged prostate (difficulty passing water);
- if you suffer from any bowel disorders;
- if you suffer from any liver or kidney problems;
- if you suffer from heart or blood pressure problems;
- if you have been told by your doctor that you have an intolerance to some sugars;
- if you have Gilbert's Syndrome (familial non-haemolytic jaundice);
- if you are taking other medicines that can affect the liver;
- if you have glucose-6-phosphate dehydrogenase deficiency;
- if you have haemolytic anaemia;
- if you are dehydrated;
- if you have had poor diet such that the diet causes health problems;
- if you weigh less than 50kg;
- if you are elderly.

If you have any of these conditions, your doctor or pharmacist will advise you about how best to use **Veganin Plus**

They may reduce the dose or increase the time interval between doses of your medicine.

During treatment with **Veganin Plus**, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Talk to your doctor or pharmacist before taking **Veganin Plus**

- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances

Taking codeine (an active ingredient of this medicine) regularly for a long time can lead to addiction and misuse, which may result in overdose and/or death.

Do not take this medicine longer than needed. Do not give this medicine to anyone else.

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.

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.

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**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and/or codeine and must not be taken while you are taking **Veganin Plus**
- if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs);
- medicines used to relax you or to help you sleep (such as benzodiazepines);
- medicines for high cholesterol levels or for the treatment of diarrhoea (cholestyramine);
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide);
- medicines to prevent blood clots (such as warfarin);
- medicines for the treatment of gout (probenecid);
- medicines for eye infections (chloramphenicol);
- anticonvulsants and medicines used to treat epilepsy (such as barbiturates);
- oral contraceptive steroids.

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of this medicine 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 this medicine 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.

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 pass 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.

Children aged less than 12 years:

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.

4. Possible side effects

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

Prolonged regular use, except under medical supervision, may lead to addiction and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you need to take the medicine for longer periods of time or you need to take more than the recommended dose or feel irritable and restless when you stop taking the medicine, you may be addicted. In any of these apply to you, it is important that you talk to your doctor.

This medicine may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. You may also become constipated. You may experience problems with your blood which means that you may bleed or bruise easily (known as thrombocytopenia) or which makes it more likely that you may get an infection (known as agranulocytosis).

If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately.

Taking any type of pain reliever for headaches too often or for a too long period of time can make them worse. If this situation happens to you talk to your doctor or pharmacist.

Frequency “Not known” (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sweating, sometimes with breathing problems, or swelling of the lips, tongue, throat or face;
- unusual bleeding or bruising under the skin
- skin rash or peeling of the skin which may be accompanied by mouth ulcers;
- severe skin reactions such as severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and formation of blisters containing pus;
- 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);
- cloudy urine or urinary retention;
- nervousness and tremor;
- hallucinations and nightmares;
- fast or irregular heartbeat;
- blurred vision;
- facial flushing;
- constipation.

These effects go away once you stop taking the medicine. If any of these effects occur, or get serious, or if you notice any other side effect not listed in this leaflet, stop taking this medicine, and tell your doctor or pharmacist immediately.

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 this medicine

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

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 store above 25°C.

Keep the tablets in the original packaging to protect from light and moisture

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

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

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