

VESANOID® SOFT-GELATIN CAPSULE

Tretinoin (10mg)

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What *Vesanoïd*® is used for

Vesanoïd® is intended to treat acute promyelocytic leukemia (APL), a type of blood cancer.

In combination with chemotherapy, all-*trans* retinoic acid increases the duration of survival, reduces the risk of relapse compared to chemotherapy alone.

How *Vesanoïd*® works

Vesanoïd® contains the active ingredient tretinoin, which is also called all-*trans* retinoic acid.

Vesanoïd® is a retinoid which works to stop or slow the growth of cancer-causing cells. It targets cancer cells rather than normal, healthy cells.

Before you use *Vesanoïd*®

Tell your doctor before taking *Vesanoïd*® if you ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes.

Mental health problems

Your mood may be affected while taking *Vesanoïd*®. You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.

- When you must not use it

Do not take *Vesanoïd*® if you have hypersensitivity to all-*trans* retinoic acid or any of its components.

Pregnancy and lactation

Do not take *Vesanoïd*® if you are pregnant, trying to get pregnant or think you may be pregnant unless the benefit of all-*trans* retinoic acid treatment outweighs the risk of foetal abnormalities due to the severity of the condition and the urgency of treatment.

Do not take *Vesanoïd*® if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Female patients of childbearing age should check with their doctor or pharmacist before taking *Vesanoïd*®.

- Taking other medicines

Tell your doctor if you are taking

- Medication that affect liver enzymes including azole antifungals (e.g. fluconazole, voriconazole, posaconazole), cimetidine, erythromycin, verapamil, diltiazem, rifampicin, glucocorticoids, phenobarbital, pentobarbital and ciclosporin.
- Antifibrinolytic agents such as tranexamic acid, aminocaproic acid and aprotinin, which help blood to form clots.
- Agents known to cause high blood pressure inside the skull such as tetracyclines (antibiotics).
- Vitamin A

Or any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use *Vesanoïd*®

- How much to use

Always take or give this medicine to your children exactly as your doctor or pharmacist has told to you. Check with

your doctor or pharmacist if you are not sure. This is approximately 8 capsules per patient per day.

The dose is normally reduced for children with intractable headache, or if you have kidney and/or liver insufficiency.

- When to use it

Take your medicine with meal or shortly thereafter.

- How long to use it

Continue taking *Vesanoïd*® for as long as your doctor recommends.

Treatment is usually 30 to 90 days. After this, you may receive a different course of chemotherapy.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

In case of overdose with all-*trans* retinoic acid, signs such as headache, nausea, vomiting, skin and mucous membrane symptoms can appear.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell your doctor immediately if you become pregnant while taking this medication.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

- Things you must not do

Do not take any new medicines without

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consulting your doctor or pharmacist.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Pregnancy:

You must use strict birth control for at least one month before you start *Vesanoïd*®, for the whole time you are taking *Vesanoïd*® and for at least one month after you finish taking *Vesanoïd*®.

You must have a pregnancy test once a month while you are taking *Vesanoïd*®.

All-*trans* retinoic acid is likely to cause a deformed infant if taking all-*trans* retinoic acid during pregnancy, irrespective of the dose or duration of the treatment.

Micro-dosed progestogen preparations (“minipill”) may be an inadequate method of contraception during treatment with all-*trans* retinoic acid.

Vesanoïd contains sorbitol; therefore, patients with rare hereditary problems of fructose intolerance should not take *Vesanoïd*.

Side effects

Selected side effects (a-d)

a) “Differentiation Syndrome” (DS) is frequently associated with increased white blood cells.

Signs of DS is fever, shortness of breath or difficulties in breathing, retained fluid, low blood pressure, swelling, weight gain, liver, kidney and multi-organ failure.

b) Increased risk blood clot in blood

vessels which may involve any organ system, during the first month of treatment. Stroke, heart attack, inadequate blood supply to kidney have been reported uncommonly.

c) Increased risk for high blood pressure in the skull when taking *Vesanoïd*® with other agents such as tetracyclines.

d) Hypervitaminosis A syndrome

Skin: dryness, redness and rash, itching, sweating, hair loss, genital ulceration and Sweet’s syndrome (sudden onset of fever with small red bumps on the arms, neck, back, or face) have been reported uncommonly. Erythema nodosum (a skin disorder characterized by painful red lumps appearing mostly on the shins) has been reported rarely.

Mucous membranes: inflammation of the lips, dryness of mouth, nose, conjunctiva (a membrane that lines the outer eye, and inner part of the eyelid) and other mucous membranes, without or with inflammatory symptoms.

Central nervous system: headache, raised pressure within the skull (mainly in children), fever, shivering, dizziness, confusion, anxiety, depression, tingling sensation, sleeping difficulty, malaise.

Neuro-sensory system: vision and hearing disorders.

Musculo-skeletal system: bone pain, chest pain. Muscle inflammation has been reported rarely.

Gastrointestinal tract: nausea, vomiting, abdominal pain, constipation, diarrhea, diminished appetite, pancreas inflammation.

Metabolic, liver and kidney dysfunctions: elevation in blood triglycerides, cholesterol, transaminases (ALAT, ASAT), creatinine. Occasional cases of

high blood calcium level have been reported.

Cardiovascular system: Irregular heartbeat, flushing. Inflammation of the myocardial muscle (myocarditis) or inflammation of the pericardium outside the heart (pericarditis) which can lead to breathlessness, palpitation, or chest pain.

Blood: Thrombocytosis (surplus of platelets) has been reported rarely. Marked basophilia (surplus of a type of white blood cells) with or without symptomatic hyperhistaminaemia (surplus of histamine in the blood) has been reported rarely.

Others: Vasculitis (inflammation of blood vessel), predominantly involving the skin, has been reported rarely.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Vesanoïd*®

- Storage

- Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture. Keep the bottle in the outer carton to protect the capsules from light.
- This medicine should not be used after the expiration date (EXP) shown on the outer pack.
- Keep out of reach of children

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will

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help to protect the environment.

Serial Number

NPRA (R1/3) 12012024/016

Product Description

- What it looks like

An oval shaped capsule with the colour of the first half orange yellow, opaque and the other half reddish brown opaque.

- Ingredients

- Active ingredient

Each soft capsule contains 10 mg of all-*trans* retinoic acid (ATRA, tretinoin)

- Inactive ingredients

- Yellow beeswax
- Hydrogenated soybean oil
- Partially hydrogenated soybean oil
- Soybean oil
- Gelatin
- Glycerol
- Karion 83 (sorbitol, mannitol, starch (maize))
- Titanium dioxide slurry with glycerol
- Yellow iron oxide slurry with glycerol
- Red iron oxide slurry with glycerol
- Purified water

MAL number:

MAL19960996ACRZ

Manufacturer

Catalent Germany Eberbach GmbH
Eberbach, Germany.

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana
Jaya, 47301 Petaling Jaya,
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Date of revision

15/01/2024