Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a doctor's prescription only

Curatane 5 mg Soft gelatin capsules

Curatane 10 mg Soft gelatin capsules

Curatane 20 mg Soft gelatin capsules

Curatane 30 mg Soft gelatin capsules

Curatane 40 mg Soft gelatin capsules

Composition:

Each capsule contains: 5 mg isotretinoin	Each capsule contains: 10 mg isotretinoin	Each capsule contains: 20 mg isotretinoin	Each capsule contains: 30 mg isotretinoin	Each capsule contains: 40 mg isotretinoin

Inactive ingredients and allergens: See section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.
Keep this leaflet. You may need to read it again.

In addition to the patient information leaflet, Curatane has a patient information brochure. This brochure contains important safety information that you need to know before starting treatment with Curatane, and which you must follow. Read the patient information brochure and patient information leaflet before using this medicine. Keep the brochure in case you need to read it again.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for children under the age of 12.

Important information that you should read:

Special warnings for women/teenage girls

Curatane is highly likely to harm an unborn baby (in medical language: the medicine is teratogenic) – it can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (the thymus gland and the parathyroid gland). It also increases the risk of miscarriage. This may happen even if Curatane is taken only for a short time during pregnancy. Therefore:

1. **You must not take Curatane if you are pregnant or think you might be pregnant.**
2. **You must not take Curatane while breastfeeding. There is a high chance that the medicine will pass into your breast milk and harm your baby.**
3. **You must not take Curatane if you could get pregnant during treatment.**
4. **You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.**

5. You must use contraceptives during the course of treatment and for one month after completing treatment.

Due to the risk of birth defects (damage to the unborn baby), Curatane is given to women of child-bearing age, on condition that they comply with the following precautionary measures:

1. Begin treatment with Curatane **only in case of severe acne**, after other treatments (such as ointments and creams or antibiotics) have failed.
2. Before treatment, your doctor must confirm that **you are not pregnant**. In addition, your doctor must explain all the risks of **birth defects** during the course of treatment. You must understand that **you must not become pregnant during the course of treatment** and what you must do to prevent getting pregnant.
3. Your doctor must provide you with **information about the contraceptives** that you must use to prevent pregnancy. Your doctor must refer you to a specialist who will advise a contraceptive method that is right for you.
4. Continuously use **at least one effective contraceptive method** (for example an intra uterine device or contraceptive implant), or two effective contraceptive methods that work in different ways (for example a hormonal contraceptive pill and a condom), for one month before starting treatment, during the course of treatment, and for one month from the day treatment is stopped. Before starting treatment with Curatane, your doctor will ask you to take a pregnancy test, which must be negative for you to be able to start taking the medicine.
5. **You must use contraceptives even if you are not menstruating** or are not sexually active (unless your doctor decides this is unnecessary).
6. **You must be capable of complying with the mandatory contraception requirements listed in this leaflet.**
7. **You must agree to see your doctor once a month for follow up** and to have additional pregnancy tests that your doctor may order. You may be asked to take a pregnancy test one month after stopping treatment with Curatane. You must not get pregnant during the course of treatment with Curatane and for one month after completing treatment, because some medicine may still be left in your body.
8. Your doctor will discuss all these points with you, using a checklist. This is a way for your doctor to confirm that you have been told about all the risks and that you will follow the rules described above.

If, despite all the precautionary measures, you become pregnant during the course of treatment with Curatane and up to one month from stopping treatment, **stop taking the medicine immediately** and contact your doctor. Your doctor may refer you to another specialist for consultation.

Your doctor will give you the 'Curatane Patient Information Brochure' which provides information about pregnancy and contraceptives. If you have not yet received the brochure, please ask your doctor for it.

Prescriptions for women capable of pregnancy are restricted to 30 days of treatment. You will need a new prescription to continue treatment. **Prescriptions are valid for 7 days from date of issue.**

Special warnings for men:

- Treatment with Curatane probably do not damage the sperm. Very small amounts of medicine may reach the semen during the course of treatment, but not at levels that can cause harm to an unborn baby. Be sure not to give this medicine to others, especially not to women.

When you get your first Curatane prescription, your doctor will give you the 'Curatane Patient Information Brochure' which contains important information about treatment with Curatane. Please read the brochure carefully and make sure you understand it completely before starting treatment with the medicine.

Additional warnings

Never give this medicine to another person. Give any unused capsules to your pharmacist at the end of treatment.

Do not donate blood during treatment with Curatane and for one month after stopping treatment. This is because if a pregnant patient receives your blood, her baby may be born with birth defects.

Mental health problems

You may not notice any changes in your mood and behavior, 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 tell to your doctor about.

1. What is the medicine intended for?

Curatane is used to treat severe acne that does not respond to other medicinal treatment, such as ointments/creams or antibiotics.

Therapeutic group: Curatane contains the active ingredient isotretinoin, which is a derivative of Vitamin A and belongs to the retinoid group (for treating acne).

Treatment with Curatane must be supervised by a dermatologist.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient isotretinoin or to peanuts or soya or any of the other ingredients that this medicine contains. See details in section 6 'Additional information'.
- You are pregnant or suspect you might be pregnant.
- You are breastfeeding.
- You are capable of becoming pregnant but are unable or unwilling to follow the guidelines for preventing pregnancy that are listed under 'Special warnings for women/teenage girls' about using this medicine.
- You have a liver disease.
- You have very high blood fat levels (such as cholesterol or triglycerides).
- You have very high Vitamin A levels in your body (hypervitaminosis A).
- You are using tetracycline antibiotics at the same time (see the section 'Other medicines and Curatane').

If any of the conditions above apply to you, ask your doctor for advice before taking Curatane.

Warnings for all patients:
Before taking Curatane talk to your doctor:

- **if you have ever had any mental illnesses/problems.** This includes depression, tendency to aggressiveness, psychosis, or changes in mood, and also thoughts

about harming yourself or ending your life. This is because your mood may be affected when you take Curatane. Tell your doctor if you have ever taken medicines for any of these disorders or are taking medicines to treat any of these conditions.

Additional warnings

- Tell your doctor if you experience persistent pain in your lower back or buttocks during treatment with Curatane. These symptoms may be signs of sacroiliitis, a type of inflammatory lower back pain. Your doctor may discontinue treatment with Curatane and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including imaging modalities such as MRI.
- **Severe skin reactions** such as erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis **have been reported with Curatane use.** The rash may develop into widespread blisters or skin peeling. You must also look out for ulcers in your mouth, throat, nose, genitals, and for conjunctivitis (red puffy eyes).
- **In rare cases, Curatane may cause severe allergic reactions;** some of these may affect the skin in the form of eczema, hives, and bruises or red patches on the hands and legs. If you develop an allergic reaction, stop taking Curatane and see a doctor urgently. Be sure to mention that you are taking this medicine.
- **Reduce intensive exercise and physical activity.** Curatane may cause muscle and joint pain, especially in children and teenagers who engage in vigorous physical activity.
- **An association has been found between Curatane and inflammatory bowel disease.** Your doctor will stop your Curatane treatment if you have severe bloody diarrhea with no history of digestive tract disorders.
- **Curatane may cause dry eyes and intolerance of contact lenses, and vision problems including reduced night vision.** Cases of dry eyes not resolving after discontinuation of therapy have been reported. Tell your doctor if you have these symptoms. Your doctor may ask you to use an eye lubrication ointment or artificial tears. If you use contact lenses and you have developed intolerance to them, you may have to wear glasses during the course of treatment. Your doctor may refer you to a specialist if you develop vision problems, and you may have to stop taking Curatane.
- **Benign intracranial hypertension has been reported during treatment with Curatane** in some cases when Curatane was taken together with tetracyclines (a type of antibiotic). Stop taking Curatane and see a doctor urgently if you experience symptoms such as headache, nausea, vomiting, and visual disturbances. Your doctor may refer you to a specialist to check for swelling of the optic disk in your eye (papilledema).
- Curatane may **lead to elevated liver enzyme levels**. Your doctor will perform blood tests to measure these levels before, during and after treatment with Curatane. If liver enzyme levels remain high, your doctor may lower the Curatane dosage or decide to discontinue treatment.
- **Curatane commonly increases blood fat levels** (such as cholesterol, triglycerides). Your doctor will perform blood tests to measure these levels before, during and at the end of treatment. It is advisable to avoid alcoholic beverages or at least reduce your usual alcohol consumption while you are on Curatane. Tell your doctor if you have high levels of fat in your blood, diabetes (high levels of sugar in your blood), you are overweight, or if you are alcohol dependent. It may be necessary to have more frequent blood tests. If your blood fat levels remain high, your doctor may reduce your dose of Curatane or decide to stop treatment.

- **Tell your doctor if you have kidney problems.** Your doctor may start you on a lower dose of Curatane and increase it later to the highest dose you are able to tolerate.
- Curatane may **lead to elevated blood sugar levels**. In rare cases, patients have become diabetic. Your doctor may monitor your blood sugar levels during treatment, especially if you are already diabetic, if you are overweight, or if you have become dependent on alcohol.
- Treatment may cause **dry skin**. It is recommended to use moisturizers for the skin and lips during the course of treatment. To prevent skin irritation, avoid using exfoliating or anti-acne products.
- **Avoid excessive exposure to the sun and use of tanning lamps and beds**. Your skin may be more sensitive to the sun. Before going out into the sun, use a sunscreen with a high skin protection factor (SPF 15 or higher).
- **Abstain from all cosmetic treatments**. Curatane may cause your skin to be more fragile. Abstain from wax epilation, from mechanical skin peeling (dermabrasion), and from laser treatments during the course of treatment with Curatane and for at least 6 months after completing treatment. These treatments may cause scarring, skin irritation or, in rare cases, changes in skin color.

Children and adolescents
This medicine is not intended for children under the age of 12, because its safety and efficacy under this age are not known.
Do not use Curatane to treat prepubertal acne and not in children aged less than 12 years of age.

Tests and follow-up
Before you start using this medicine, your doctor will refer you to a blood test to monitor your liver enzymes and level of fat in your blood. If necessary, your doctor will monitor your blood sugar (see section 2 'Warnings for all patients').
Before you start treatment, your doctor will ask you to take a pregnancy test. The test must be negative for you to start taking the medicine. Women taking this medicine must see their doctor once a month for follow-up and for a pregnancy test according to their doctor's decision (see 'Special warnings for women/teenage girls').

Other medicines and Curatane
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.
Do not take Vitamin A supplements or tetracycline antibiotics or use other acne treatments during treatment with Curatane. You may use moisturizers or emollients (creams or skincare products which prevent water loss from the skin and have a softening effect on the skin).
Do not use other local acne treatments that cause skin peeling while you are taking curatane.

Use of the medicine and food
Do not chew! Swallow the capsules whole, on a full stomach, with some fluids or a small amount of food.

Using the medicine and alcohol consumption
It is advisable to avoid alcoholic beverages, or at least reduce the amount of alcoholic beverages you usually consume, while you are being treated with Curatane.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

For more information about contraceptives, pregnancy, and breastfeeding, read the section 'Important information that you should read' at the beginning of this leaflet.

Pregnancy
Do not use Curatane when pregnant. If you are capable of becoming pregnant you must use effective contraceptives for one month before starting treatment with Curatane, during treatment, and for one month after completing treatment.
If you become pregnant during the course of treatment with Curatane or during the month after completing the treatment, **stop taking the medicine immediately** and consult your doctor. Your doctor may refer you to a specialist for consultation.
If you have used Curatane while pregnant, Curatane can harm your unborn baby (in medical language the medicine is teratogenic). **This medicine also increases the chance of miscarriage.**
Curatane may cause severe defects in the unborn baby's brain, face, ears, eyes, heart, and certain glands (the thymus gland and parathyroid gland).

Breastfeeding
Use of this medicine while breastfeeding is prohibited.
There is a high chance that the medicine will pass into your breastmilk and harm your baby.

Driving and use of machines
You may experience disturbed night vision during the course of treatment. This effect can occur suddenly and in rare cases continues after treatment is discontinued. There are also some very rare reports of drowsiness and dizziness during the course of treatment. If you suffer from these effects, do not drive or operate machines.

Important information about some of this medicine's ingredients
Curatane contains sorbitol and soya oil.
Each 5 mg capsule contains 4.99 mg sorbitol.
Each 10 mg capsule contains 5.30 mg sorbitol.
Each 20 mg capsule contains 16.98 mg sorbitol.
Each 30 mg capsule contains 21.50 mg sorbitol.
Each 40 mg capsule contains 23.75 mg sorbitol.

If you are sensitive (allergic) to peanuts or soy, do not take this medicine.

3. How should you use the medicine?

Always use this medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

The usual starting dosage is: 0.5 mg per kg body weight per day (0.5 mg/kg/day), so if you weigh 60 kg, your treatment will usually start at a dose of 30 mg a day.
A few weeks after starting treatment, the doctor may change your dosage, depending on your response to treatment. For most patients the dose will be between 0.5-1.0 mg/kg/day. If you feel that your dose is too high or too low for you, consult your doctor.

If you have severe kidney problems, you will probably be treated with a lower starting dose (such as 10 mg a day) which will be raised to the highest dose that your body can tolerate. If your body cannot tolerate the recommended dose, you may be given a lower dose: this means that your treatment will continue for longer and there is a higher chance of your acne coming back.

Do not exceed the recommended dose.

Directions for use
Do not chew! Swallow the capsules whole, on a full stomach, with some fluids or a small amount of food. The capsules can be taken once or twice a day, as per the instructions.

Treatment duration
Curatane treatment usually continues for 16 to 24 weeks. Most patients require only one treatment cycle. Your acne may continue to improve for up to 8 weeks after completing treatment with Curatane. This is the reason that a further treatment cycle will not be started until 8 weeks after completing treatment.
Sometimes, the acne can get worse during the first weeks of treatment, but it usually improves with continued treatment.

If you took an overdose, or if another person or a child has accidentally swallowed some medicine, consult a doctor or proceed to a hospital emergency room immediately, and bring the medicine package with you.

If you forgot to take this medicine at the scheduled time, take it as soon as possible, unless it is almost time for the next dose. In this case, skip the dose you forgot and continue taking treatment from the next dose as usual. Do not take a double dose to make up for a forgotten dose.

Persist with the treatment as recommended by the doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like all medicines, using Curatane may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them. Some of the side effects associated with the use of isotretinoin are related to the dose. The side effects are usually reversible after changing the dose or stopping treatment. However, some side effects may continue even after treatment has stopped. Some side effects can be serious and you will have to consult your doctor immediately.

Side effects that require immediate medical attention

Skin problems
<u>Side effects of unknown frequency (frequency cannot be estimated from available data):</u>

- Serious skin rashes (erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), which may be life-threatening and therefore require immediate medical intervention. They first appear as round patches often with central blisters, usually on the arms and hands or on the legs and feet. More severe rashes can also include blisters on the chest and back. Additional symptoms which may occur include eye

infections (conjunctivitis) or ulcers in the mouth, throat or nose. Severe rashes may develop into widespread peeling of the skin which can be life-threatening. These severe rashes are often preceded by headache, fever and body aches (flu-like symptoms).

If you develop a severe rash or the skin symptoms described above, stop taking Curatane and consult your doctor immediately.

Mental health problems

Rare side effects (appear in up to one in 1,000 users):

- Depression or related disorders. Signs of this are a feeling of sadness, mood swings, anxiety, or emotional discomfort.
- Worsening of pre-existing depression.
- Developing violent or aggressive behavior.

Very rare side effects (appear in up to one in 10,000 users):

- Some patients have developed self-destructive or suicidal thoughts (suicidal ideation), have tried to end their lives (tried to commit suicide), or have ended their lives (committed suicide). These patients may not appear to be depressed.
- Unusual behavior.
- Signs of psychosis: losing touch with reality, such as: hearing or seeing things that do not exist.

If you experience any sign of the mental effects described above, consult your doctor immediately. Your doctor may tell you to stop taking Curatane. It is possible that discontinuing Curatane will not make the effects disappear. You may need additional help and your doctor can help you with this.

Allergic reactions

Rare side effects (appear in up to one in 1,000 users):

Severe reactions (anaphylactic): difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips, and mouth, as well as sudden swelling of the hands, feet, and ankles.

Very rare side effects (appear in up to one in 10,000 users):

Sudden pressure in the chest, shortness of breath and wheezing, especially if you have asthma.

If you have a severe reaction, seek emergency medical help immediately.

If you have any sort of allergic reaction, stop taking Curatane and consult your doctor.

Bones and muscles

Side effects whose frequency is unknown (frequency cannot be estimated from available data):

Muscle weakness which can be life-threatening, may be experienced as difficulty moving your arms or legs, painful, puffy, bruised areas in your body, dark colored urine, passing less or no urine, confusion or dehydration. These are signs of rhabdomyolysis, breakdown of muscle tissue which can result in kidney failure. This could happen if you engage in intensive physical activity during treatment with Curatane.

Liver and kidney problems

Very rare side effects (appear in up to one in 10,000 users):

- Yellow skin or eyes and feeling tired - these can be signs of inflammation of the liver (hepatitis). **Stop taking Curatane immediately and consult your doctor.**
- Difficulty passing urine, puffy eyelids, feeling excessively tired - these can be signs of inflammation of the kidneys. **Stop taking Curatane immediately and consult your doctor.**

Nervous system problems

Very rare side effects (appear in up to one in 10,000 users):

- Persistent headache, accompanied by nausea, vomiting and changes in vision, including blurred vision - these can be signs of benign intracranial hypertension, especially if Curatane is taken concomitantly with tetracyclic antibiotics. **Stop taking Curatane immediately and consult your doctor.**

Bowel and stomach problems

Very rare side effects (appear in up to one in 10,000 users):

- Severe abdominal pain, with or without severe bloody diarrhea, nausea, and vomiting - these can be signs of severe intestinal problems. **Stop taking Curatane immediately and consult your doctor.**

Eye problems

Very rare side effects (appear in up to one in 10,000 users):

- Blurred vision.

If your vision becomes blurred, stop taking Curatane immediately and consult your doctor. If your vision is impaired in any other way, consult your doctor as soon as possible.

Additional side effects

Very common side effects (appear in more than one in 10 users):

- Dryness of the skin, especially in the area of the lips and face; inflamed skin; chapped and inflamed lips; rash; itching and slight skin peeling. Use a skin moisturizing product when you start treatment.
- Skin is more fragile and redder than usual, especially in the face area.
- Back pain; muscle pain; joint pain, especially in children and teenagers.
  To prevent bone and muscle problems from getting worse, reduce vigorous physical activity during treatment with Curatane.
- Inflammation of the eyes (conjunctivitis) and eyelid area, dry and irritated eyes. Consult the pharmacist regarding suitable eye drops. If you wear contact lenses and suffer from dry eyes, you may have to wear glasses instead of contact lenses.
- Elevated liver enzyme levels in blood tests.
- Changes in fat levels in your blood (including HDL or triglycerides).
- Bruising, bleeding, or blood clotting more easily (in cases where blood clotting cells are affected).
- Anemia, which may manifest as weakness, dizziness, pale skin (in cases where red blood cells are affected).

Common side effects (appear in up to one in 10 users):

- Headache.
- Rise in cholesterol levels in your blood.
- Blood or protein appearing in the urine.

- Increased chance of infection - in cases where white blood cells are affected.
- Dryness and crusting of the inner part of the nose, an effect which causes mild nosebleed.
- Sore or inflamed throat and nose.
- Allergic reactions such as rash and itching. If you have an allergic reaction, stop taking Curatane and consult your doctor.

Rare side effects (appear in up to one in 1,000 users):

- Hair loss (alopecia). This effect is usually temporary. Your hair is expected to return to its normal condition after completing treatment.

Very rare side effects (appear in up to one in 10,000 users):

- Impaired night vision. Color blindness and color vision get worse.
- Increased sensitivity to light - you may feel a need to wear sunglasses to protect your eyes from sunlight that is too strong.
- Other vision problems, including blurred vision, distorted vision, sensation of "cloudiness" in the eyes (corneal opacity, cataract).
- Excessive thirst, frequent need to urinate, blood tests showing an increase in sugar levels - these can all be signs of diabetes.
- Acne can get worse during the first few weeks of treatment, but the symptoms are expected to improve with continued treatment.
- Skin inflammations, swollen skin, darker skin than usual, especially in the face area.
- Excessive sweating or itching.
- Arthritis; bone disorders (delayed growth, excessive growth, and changes in bone density); growing bones may stop growing.
- Calcium deposits in soft tissues, sore tendons, high levels of muscle breakdown products in the blood, if you exercise vigorously.
- Bacterial infections in the tissue at the base of the fingernail, changes in the fingernails.
- Swelling, discharge, pus.
- Thickened scarring after surgery.
- Increased body hair.
- Convulsion, drowsiness, dizziness.
- Swelling of the lymph nodes.
- Dryness in the throat, hoarseness.
- Hearing difficulties.
- Feeling generally unwell.
- High levels of uric acid in the blood.
- Bacterial infections.
- Inflammation of blood vessels (sometimes accompanied by bruises and red patches).

Side effects whose frequency is unknown (frequency cannot be estimated from available data):

- Dark-colored or cola-colored urine.
- Problems achieving or maintaining an erection.
- Reduced libido.
- Breast swelling in males, with or without tenderness.
- Vaginal dryness.
- Sacroiliitis, a type of inflammatory back pain causing pain in your buttocks and lower back.

- Inflammation of the urethra.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult the doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How should the medicine be stored?

Avoid poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the blister and package. The expiry date refers to the last day of that month.
Storage conditions
Store in a dry place, at a temperature below 25°C in the original package. Keep the capsules inside the blister tray inside the outer carton, to protect them from moisture and light.

6. Additional information

In addition to the active ingredient this medicine also contains:
Curatane 5 mg –
soya oil, gelatin, purified water, glycerol, sorbitol (liquid), beeswax yellow, titanium dioxide, DL-alpha-tocopherol, vegetable oil hydrogenated, disodium edetate, butylated hydroxyanisole.
Curatane 10 mg –
soya oil, gelatin, glycerol, purified water, sorbitol (70% solution), beeswax yellow, DL-alpha-tocopherol, titanium dioxide, vegetable oil hydrogenated, disodium edetate dihydrate, butylated hydroxyanisole, iron oxide black, ponceau 4R.
Curatane 20 mg –
soya oil, gelatin, glycerol, sorbitol (70% solution), purified water, beeswax yellow, DL-alpha-tocopherol, vegetable oil hydrogenated, disodium edetate dihydrate, titanium dioxide, ponceau 4R, indigotine lake (indigo carmine), butylated hydroxyanisole.
Curatane 30 mg –
soya oil, gelatin, purified water, glycerol, sorbitol (liquid), beeswax yellow, All-rac-alpha-tocopherol, titanium dioxide, disodium edetate, iron oxide red, butyl hydroxynisole.
Curatane 40 mg –
soya oil, gelatin, purified water, glycerol, sorbitol (liquid), beeswax yellow, All-rac-alpha-tocopherol, titanium dioxide, disodium edetate dihydrate, butylated hydroxyanisole, sunset yellow E110.

What the medicine looks like and contents of the pack:

The capsules are packaged in blisters.
Each box of Curatane 5 mg, 10 mg, 20 mg, and 30 mg contains 30, 60 capsules.
Each box of Curatane 40 mg contains 30 capsules.
Soft, oval gelatin capsules containing opaque, thick yellow/orange liquid.
Capsule color: Curatane 5 mg - pinkish, Curatane 10 mg - purplish, Curatane 20 mg - reddish-brown, Curatane 30 mg – pink, Curatane 40 mg - light orange.
Not all pack sizes may be marketed.

License holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Manufacturer's name and address: Douglas Pharmaceuticals Ltd., Lincoln 0610, Auckland, New Zealand.

Revised in October 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Curatane 5 mg: 149-93-33752-00
Curatane 10 mg: 136-12-30295-00
Curatane 20 mg: 120-88-30099-00
Curatane 30 mg: 165-14-35822-00/01
Curatane 40 mg: 139-24-31621-00