Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Promezole 2 mg/ml
Promezole 4 mg/ml
Powder for oral suspension

Active ingredient:
Promezole 2 mg/ml: After reconstitution with water, each 1 ml of suspension contains 2 mg of omeprazole. After reconstitution with water, each bottle with 90 ml of suspension contains 180 mg of omeprazole.

Promezole 4 mg/ml: After reconstitution with water, each 1 ml of suspension contains 4 mg omeprazole. After reconstitution with water, each bottle with 90 ml of suspension contains 360 mg of omeprazole.

For the list of the inactive ingredients and allergens in the medicine – see section 6.

Important information about the inactive ingredients in this medicine - see section 2 under **'Important information about some of this medicine's ingredients'.**

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

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

1) What is this medicine intended for?

This medicine is intended for:

Adults:
- Treatment of gastric and duodenal ulcers.
- Prevention of relapse of gastric and duodenal ulcers.
- For combination treatment with antibiotics for *Helicobacter pylori* associated with peptic ulcer disease.
- Treatment of NSAID-associated gastric and duodenal ulcers.
- Prevention of NSAID-associated gastric and duodenal ulcers.
- Treatment of reflux oesophagitis.
- Long-term management of patients with healed reflux oesophagitis.
- Treatment of symptomatic gastro-oesophageal reflux disease.

Infants and children over 1 month of age:
- Treatment of reflux oesophagitis.
- Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease.

Children over 4 years of age and adolescents:
- In combination with antibiotics in treatment of duodenal ulcer caused by *Helicobacter pylori*.

Therapeutic group: Proton pump inhibitors (PPIs).
The medicine inhibits gastric acid secretion.

2) Before using this medicine:

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient or to medicines containing other proton pump inhibitors (PPIs) such as pantoprazole, lansoprazole, rabeprazole, esomeprazole or to any of the other ingredients in this medicine. The active ingredient appears at the beginning of the leaflet under 'Active ingredient', and the additional ingredients are listed in section 6.
- You are taking a medicine containing nelfinavir (a medicine for the treatment of acquired human immunodeficiency virus (HIV) infections).

Special warnings about using this medicine:
- Severe skin reactions have been reported, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms syndrome (DRESS), acute generalised exanthematous pustulosis (AGEP). Discontinue use of Promezole and seek immediate medical attention if you notice symptoms related to these severe skin reactions, described in section 4.
- If you are taking a medicine containing atazanavir (a medicine for the treatment of acquired human immunodeficiency virus (HIV) infections), your doctor may instruct you to be under close medical monitoring through the end of treatment with Promezole.

Promezole may hide the symptoms of other diseases. Therefore, if you have any of the following effects before you start treatment with Promezole or during treatment with Promezole, contact your doctor straight away:
- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You have difficulty or pain when swallowing food, nausea, vomiting of food, vomiting of blood or bloody or black stools.
- You have severe or persistent diarrhoea, as use of Promezole may slightly increase the risk of infectious diarrhoea.
- You have severe liver function problems.
- You have ever had a skin reaction after use of a medicine similar to Promezole that reduces secretion of stomach acid.
- You are due to have a specific blood test (Chromogranin A).

Additional warnings:
- Use of a proton pump inhibitor like Promezole, especially for more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).
- If you develop a rash on your skin, especially in areas exposed to the sun – tell your doctor as soon as possible, as you may need to stop your use of Promezole. Inform your doctor if you have other ill-effects like pain in your joints.
- Use of Promezole may cause inflammation of your kidneys. Symptoms may include a decrease in the amount of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should immediately report the appearance of such signs to the treating physician.
- Promezole may reduce the absorption of vitamin B12, especially if you take Promezole for a prolonged period. Contact your doctor if you notice the following symptoms that indicate a low level of vitamin B12:
  - Extreme fatigue or lacking energy
  - Feeling numbness or tingling
  - Pain or redness of the tongue, mouth ulcers
  - Muscle weakness
  - Visual disturbances
  - Memory problems, confusion, depression

Use in infants, toddlers, children and adolescents:
Promezole is intended for administration to infants over one month of age, toddlers, adolescents and adults. This medicine is not intended for use in infants under 1 month of age.
Some children may require long-term treatment with the medicine due to a chronic illness, although prolonged administration is not recommended.

Tests and follow-up:
- If you take Promezole on a long-term basis (for longer than 1 year), your doctor may instruct you to be under regular medical surveillance. You should report any new and exceptional symptom whenever you see your doctor.
- Consult your doctor regarding regular testing of the level of magnesium in your blood during treatment with this medicine.

Drug interactions:
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking the following medicines:
- nelfinavir, atazanavir (medicines for treatment of acquired human immunodeficiency disease (HIV) infections). See also section 2 'Do not use this medicine if'.
- Ketoconazole, itraconazole, posaconazole or voriconazole (for treatment of fungal infections).
- Digoxin (for treatment of heart problems).
- Diazepam (for treatment of anxiety, to relax muscles or for epilepsy).
- Phenytoin (for treatment of epilepsy). If you are taking phenytoin, your doctor will perform medical monitoring when you start or stop treatment with Promezole.
- Blood thinning medicines such as warfarin or other vitamin K blockers. Your doctor may perform medical monitoring when you start or stop treatment with Promezole.
- Rifampicin (for treatment of tuberculosis).
- Tacrolimus (in case of organ transplantation).
- St John's wort (*Hypericum perforatum*) for treatment of depression.
- Cilostazol (for treatment of intermittent claudication).
- Clopidogrel (anticoagulant).
- Erlotinib (for treatment of cancer).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking high doses of methotrexate, your doctor may consider temporarily stopping your Promezole treatment.
- Amoxicillin and clarithromycin (antibiotics) – if your doctor has prescribed these antibiotics as well as Promezole to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you inform your doctor about any other medicine you are taking.

Using this medicine and food:
You should take the medicine without food (on an empty stomach), at least 30 minutes before a meal. For more information – see section 3: 'How to use this medicine'.

Pregnancy, breastfeeding and fertility:
Pregnancy: Consult your doctor before using this medicine if you are pregnant, think you are pregnant or are planning to become pregnant. Results of clinical trials in which pregnant women took omeprazole showed that no side effects were observed in the mother, the unborn baby or the infant. Therefore, Promezole may be taken during pregnancy.

Breastfeeding: Consult your doctor before using this medicine if you are breastfeeding. Omeprazole (the active ingredient in the medicine) is excreted in breast milk, but is not likely to affect the infant when therapeutic doses are taken. Your doctor will discuss the options for taking this medicine when breastfeeding with you and whether use of the medicine is right for you during this period.

Fertility: Results of clinical trials in animals have shown that administration of oral omeprazole does not affect fertility.

Driving and using machines:
Promezole is not likely to affect your ability to drive or operate machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If you feel these effects, do not drive or operate machines.

Important information about some of this medicine's ingredients:
- Each 1 ml of oral suspension contains the following sugar alcohols: 272 mg maltitol (E965), 5 mg mannitol (E421); and the following sugar substitute: 4 mg sucralose (E955). These sugars may cause mild diarrhoea. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine. Each 1 ml of oral suspension contains less than 1 calorie.
- Each 1 ml of oral suspension contains 17.2 mg of sodium (table salt; main component of cooking); or 86 mg of sodium per 5 ml dose. A 5ml dose of suspension is equivalent to 4.3% of the recommended maximum daily dietary intake of sodium for an adult. If you are taking the medicine for long periods of time or are on a low sodium diet, consult your doctor or pharmacist before taking this medicine.
- Each 1 ml of oral suspension contains 54.3 mg of potassium; or 271.5 mg of potassium per 5 ml dose. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- Each 1 ml of oral suspension contains 2.3 mg of sodium methylparaben (sodium methyl parahydroxybenzoate; E219). Sodium methylparaben may cause allergic reactions (possibly delayed).
- Each 1 ml of oral suspension contains 5 mg of sodium benzoate (E211). Sodium benzoate may increase effects of jaundice (change in the colour of the skin and whites of the eyes to a yellow shade) in infants up to the age of 4 weeks.

3) How to use this medicine?

Always use this medicine according to your 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.
For dosages of 15 mg or less of omeprazole (the active ingredient in Promezole), it is advisable to use Promezole 2 mg/ml. Promezole 2 mg/ml may also be used for dosages between 15 mg to 20 mg of omeprazole.
For dosages of 20 mg or 40 mg of omeprazole, it is advisable to use Promezole 4 mg/ml.

The recommended dosage is usually:

Adults:
Treatment of duodenal ulcers:
- Omeprazole 20 mg once daily for two weeks. If the ulcer has not healed, your doctor may recommend continuing with this dosage for another two weeks.
- If the ulcer has not fully healed, the dosage may be increased to omeprazole 40 mg once daily for 4 weeks.

Treatment of gastric ulcers:
- Omeprazole 20 mg once daily for 4 weeks. If the ulcer has not healed, your doctor may recommend continuing with this dosage for another 4 weeks.
- If the ulcer has not fully healed, the dosage can be increased to omeprazole 40 mg once daily for 8 weeks.

Prevention of relapse of gastric and duodenal ulcers:
- Omeprazole 10 mg or 20 mg once daily. Your doctor may recommend increasing the dosage to omeprazole 40 mg once daily.

Treatment of ulcers caused by *Helicobacter pylori* infection and prevention of their recurrence:
- Omeprazole 20 mg twice daily for one week.
- Your doctor will also recommend taking two types of antibiotics from the three following options: amoxicillin, clarithromycin and metronidazole.

Treatment of nonsteroidal anti-inflammatory drug (NSAID)-associated gastric or duodenal ulcers:
- Omeprazole 20 mg once daily for 4-8 weeks.

Prevention of nonsteroidal anti-inflammatory drug (NSAID)-associated gastric or duodenal ulcers in patients at risk:
- Omeprazole 20 mg once daily.

Treatment of reflux oesophagitis:
- Omeprazole 20 mg once daily for 4 weeks. If the inflammation has not healed, your doctor may recommend continuing treatment for another 4 weeks.
- In cases of severe inflammation, the doctor may order a dosage of omeprazole 40 mg once daily for 8 weeks.

Long-term management of patients with healed reflux oesophagitis:
- Omeprazole 10 mg once daily. Your doctor may recommend a dosage of omeprazole 20 mg or 40 mg once daily.

Treatment of symptomatic gastro-oesophageal reflux disease:
- Omeprazole 10 or 20 mg once daily for 4 weeks. If after 4 weeks of treatment, the oesophagus has not healed with treatment of omeprazole 20 mg, the doctor may recommend performance of additional tests to investigate your medical condition.

Infants, children and adolescents:
Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease:
- **Infants over 1 month of age may take Promezole.** The dosage for infants and toddlers is determined according to their weight. The doctor may decide to correct the dosage also based on the information in the following table:

Age	Weight	Dosage
1 month to 12 months of age	-	1 mg/kg once daily. Dosage above 1.5 mg/kg/day have not been studied.
1 year of age or older	10-20 kg	10 mg once daily. The dosage can be increased to 20 mg once daily if needed.
2 years of age or older	> 20 kg	20 mg once daily. The dosage can be increased to 40 mg once daily if needed.

Treatment of ulcers caused by *Helicobacter pylori* infection and prevention of their recurrence:
- **Children aged over 4 years may take Promezole.** The dosage for children is based on the child's weight, and the doctor will decide the correct dose.
- The doctor will also recommend taking two antibiotics: amoxicillin and clarithromycin.

How to use:
Promezole 2 mg/ml: Each 5 ml of oral suspension contains 10 mg of omeprazole.
Promezole 4 mg/ml: Each 5 ml of oral suspension contains 20 mg of omeprazole.

Do not take the dry powder in the cap or bottle. Reconstitute the powder with water before using the medicine. See the detailed instructions for preparing the powder for use later in this section (section 3: 'How to use this medicine?').
Do not exceed the recommended dose.
Shake well before use. The medicine should only be removed from the bottle with the enclosed syringe.
You should take the medicine without food (on an empty stomach), at least 30 minutes before a meal. It is recommended that you take the medicine in the morning.

Patients with difficulty swallowing:
This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tube.
Instructions for use via NG or PEG tube:
- Ensure that the enteral feeding tube is free from anything that could be an obstruction before administration of the medicine.
- Flush the enteral tube with 5 ml of water.
- Using the measuring syringe provided with the medicine, insert the required dose of Promezole into the enteral tube.
- Flush the enteral tube again with 5 more ml of water.

Promezole can be administered using enteral tubes made of Polyurethane or PVC; and with diameters of between 6 Fr. to 16 Fr.

Preparation instructions:
The medicine is supplied in a "2 compartment bottle" package. The powder is in the bottle itself and in the bottle's special cap. The two powders first need to be combined and only then is the water to be added to the bottle. A red disk will drop from the cap – it helps mix the blend of powders together and also mix the blend of powders with the water. After preparing the suspension, keep the red disk in the bottle (do not remove it from the bottle). After adding the water and obtaining a suspension, the red cap is replaced by a grey cap.
It is recommended that you have a pharmacist at the pharmacy prepare the suspension for use.

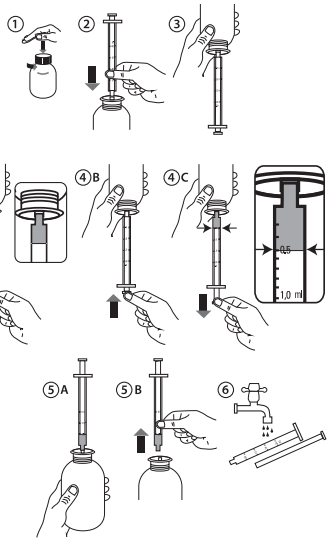
Preparation instructions – stage 1: Mix the two powders together (the powder in the cap with the powder in the bottle)
- Shake the bottle for 10 seconds to loosen the powders in the bottle and cap.
- Twist the red cap anti-clockwise (twist to the left - see the illustration on the cap) until the seal is broken to release the powder in the cap into the base of the bottle.
- Twist the red cap back to the original position (twisting to the right, clockwise) to securely fasten it onto the bottle.

Preparation instructions – stage 2: Addition of water to the blend of powders to obtain a liquid suspension
- Shake the bottle vigorously for 10 seconds to mix the two powders in the bottle well.
- Tap the base of the bottle 3 times on a hard and stable horizontal surface (such as the kitchen counter) to make sure all powder mix reaches the base of the bottle and that there is no powder stuck in the cap.
- Remove the red cap from the bottle.
- Add 64 ml of water by using a measuring device. Fill water up to the line on the bottle.
- Securely fasten the red cap onto the bottle and shake the bottle vigorously for 30 seconds.

Preparation instructions – stage 3: Placement of syringe adaptor
- Remove the red cap and red ring. Throw them in the trash.
- Attach the colourless, transparent bottle adaptor to the tip of the bottle. Close the bottle with the grey cap.
- Leave the bottle closed for 15 minutes to allow the suspension to reach the final consistency.

Preparation instructions – 4th and final stage: Measuring the dose in the syringe
Instructions for use of the syringe:
A. Shake the closed bottle for 20 seconds prior to each use.
B. To open the bottle, press the grey cap down and turn it anti-clockwise (twist to the left –see Figure 1). Do not remove the white cap portion.
C. Insert the syringe into the special adaptor opening (see Figure 2).
D. Turn the bottle upside down, with the syringe connected to the bottle adaptor (see Figure 3).
E. Fill the syringe with a small amount of suspension by pulling the plunger slightly down (see Figure 4A). Then push the plunger upward in order to remove any possible bubbles from the syringe (see Figure 4B). Now pull the syringe plunger down again to fill the volume of suspension recommended by your doctor. The top of the plunger should be in line with the graduation mark that indicates the volume of suspension that needs to be filled in the syringe (Figure 4C). Use the graduation mark on the syringe to precisely fill the volume of suspension.
F. Turn the bottle so that it is vertical again (standing). The syringe remains connected to the bottle adaptor (see Figure 5A).
G. Remove the syringe from the bottle adaptor (see Figure 5B).
H. Put the tip of the syringe into the mouth of the patient and push the syringe plunger slowly to push the suspension out of the syringe into the mouth of the patient. Make sure that the syringe plunger reaches the position where it cannot be pushed in further - this indicates that all the suspension in the syringe has been administered to the patient. Note that as more suspension is released, the plunger's resistance decreases, making it easier for the rest of the suspension to be released.
I. Wash the syringe with water and put it aside to dry before you use it again (see Figure 6).
J. Close the bottle with the grey cap. Keep the bottle adaptor connected to the bottle.

Note: While using the suspension, the red plastic disc will remain in the bottle. This is normal. Do not attempt to remove the red disc.



If your condition does not improve, contact your doctor.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
If you forget to take the medicine at the scheduled time, take a dose as soon as you remember it, however, if it is almost time to take the next dose, skip the forgotten dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking this medicine: Do stop taking the medicine without consulting your doctor or pharmacist. **Adhere to the treatment as recommended by your doctor.**

Do not take medicines in the dark! Check the label and dose every time 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) Side effects:

As with any medicine, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop taking Promezole and contact a doctor immediately if you notice the following rare (affect up to 1 in 1,000 patients) or very rare (affect up to 1 in 10,000 patients) but serious side effects:
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction) (rare).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This condition could be "Stevens-Johnson syndrome" or "toxic epidermal necrolysis" (very rare).
- Yellowing of the skin, dark urine and tiredness which may be symptoms of liver problems (rare).

Additional side effects
Common side effects (affect up to 1 in 10 patients):
- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, abdominal bloating, wind (flatulence).
- Nausea or vomiting.
- Benign polyps in the stomach.

Uncommon side effects (affect up to 1 in 100 patients):
- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Hip, wrist and spinal fractures.
- Generally feeling unwell and lacking energy.

Rare side effects (affect up to 1 in 1,000 patients):
- Blood problems such as a reduced number of white cells or platelets.
- Low levels of sodium in the blood.
- Feeling agitated/anxious, confused or depressed.
- Changes in sense of taste.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth, inflammation of the inside of the mouth.
- Fungal infection of the mouth which can affect the gut.
- Inflammation of the liver with or without the appearance of signs of jaundice.
- Hair loss (alopecia).
- Light sensitivity.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (tubulointerstitial nephritis).
- Increased sweating.
- Hypersensitivity reactions e.g. fever, angioedema and/or extreme allergic reaction (anaphylactic shock).

Very rare side effects (affect up to 1 in 10,000 patients):
- Changes in blood count, including agranulocytosis (lack of white blood cells).
- Aggression.
- Hallucinations – seeing, feeling or hearing things that are not actually there.
- Severe liver problems leading to liver failure and inflammation of the brain (in people with existing liver disease).
- Erythema multiforme.
- Severe allergic reaction of the skin such as Stevens-Johnson syndrome, toxic epidermal necrolysis.
- Muscle weakness.
- Enlarged breasts in men.

Side effects of unknown frequency (frequency cannot be estimated from the available data):
- Reduced blood level of magnesium. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you have any of these symptoms, tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor the levels of magnesium in your blood. See section 2, under 'Tests and follow-up'.
- Microscopic colitis.
- Rash, which is sometimes accompanied by pain in the joints.

In very rare cases, Promezole may affect the white blood cells and lead to immune deficiency (impaired immune system). If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. In this situation, it is important that you inform the doctor about your medicine.

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 your doctor.

Reporting side effects:
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 to store the medicine?

Prevent 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 your doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage of the powder prior preparation: at a temperature below 25°C. Store in the original aluminium foil pouch to protect from light and moisture.

Storage of the ready suspension: after reconstitution store in the refrigerator (2°-8°C) in the original pack to protect from light, and keep the bottle tightly closed. Use within 28 days and no later than the expiry date of the medicine. It can be stored at a temperature below 25°C for 2 days.

6) Additional information:

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Maltitol (E965), Potassium Hydrogen Carbonate (E501), Sodium Hydrogen Carbonate (E500), Sodium Alginate (E401), Mannitol (E421), Sodium Benzoate (E211), Sucralose (E955), Titanium Dioxide (E171), Xanthan Gum (E415), Mint Flavouring [also containing Gum Arabic / Acacia Gum (E414) and Pulegone] and Sodium Methylparaben (Sodium Methyl Parahydroxybenzoate; E219)

The medicine Promezole 2 mg/ml also contains the following inactive ingredient:
Vanilla Flavouring [also containing Maltodextrin (Maize), Silicon Dioxide (E551) and Vegetable Oils and Fats].

What the medicine looks like and contents of the pack: In the cap, the medicine looks like a white / off-white/ slightly yellow powder.
In the bottle, the medicine looks like a white / off-white/ slightly yellow powder. The powder may contain dark specks due to sweetener.
The medicine is packed in a plastic bottle and a read plastic cap, both of which are packed in an aluminium foil pouch. The bottle and cap together contain 47 grams of powder. Once reconstituted, the bottle contains 90 ml of oral suspension, of which 75 ml of suspension can be drawn.
Each pack also contains a plastic syringe with a volume of 5 ml (graduated at each 1 ml and intermediate marks every 0.1 ml). a white plastic syringe adaptor that connects to the opening of the bottle and a grey replacement cap for the bottle for use after reconstituting the suspension.

Pack size: The medicine is provided in a package, as follows:
- Cardboard packages containing between 1 and 5 bottles with the accessory supplies (syringe, adaptor and cap). The number of bottles and accessory supplies in each cardboard package may change according to the size of the pack. The number of bottles and the accessory supplies in each pack appears on the package.
- Not all pack sizes may be marketed.

Registration holder: Super-Pharm (Israel) Ltd., 16 Arie Shenkar St., Herzliya 4672516.
Manufacturer: Xeolas Pharmaceuticals Ltd., Dublin, Ireland.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Promezole 2 mg/ml: 177-08-37642-99
Promezole 4 mg/ml: 177-09-37643-99

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