

PARMODIA[®] Film-coated Tablets 0.1 mg

Pemafibrate (0.1 mg)

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What PARMODIA is used for

PARMODIA is used as adjunctive therapy to diet or other nonpharmacological treatment (e.g. exercise) to reduce triglyceride (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in patients with dyslipidemia characterised by high TG ≥ 150 mg/dL, particularly when there is evidence of associated risk such as hypertension and smoking.

Dyslipidemia is an abnormal level of lipids such as TG and cholesterol, also called fats, in the blood.

How PARMODIA works

PARMODIA contains a medicine called pemafibrate. Pemafibrate activates nuclear receptor (PPAR α) by binding to this receptor and regulates the target gene expression, leading to decreased TG and increased HDL-C.

If you have any questions about how PARMODIA works or why this medicine has been prescribed to you, ask your doctor.

Before you use PARMODIA

- When you must not use it

Follow all instructions given to you by your doctor or pharmacist carefully, even if they differ from the general information contained in

this leaflet.

Do not take PARMODIA

- If you are allergic (hypersensitivity) to pemafibrate or to any of the excipients (listed in Section Product Description).
- If you have severe liver problems, moderate or severe cirrhosis, or biliary obstruction.
- If you have cholelithiasis (gallstones).
- If you are pregnant or possibly pregnant women.
- If you are receiving cyclosporine or rifampicin.

If any of these apply to you, tell your doctor and do not take PARMODIA. If you are not sure, talk to your doctor or pharmacist before taking PARMODIA.

- Pregnancy and breast-feeding

Do not take PARMODIA if you are pregnant or think that you may be pregnant.

The safety of PARMODIA has not been established for use during pregnancy.

You should tell your doctor if you are breast-feeding.

The use of PARMODIA should be avoided in breast-feeding women. This medicine may get into milk. If the use of PARMODIA is unavoidable, breast-feeding should be discontinued.

- Before you start to use it

Talk to your doctor or pharmacist before taking PARMODIA if:

- You have any allergies.
- You have liver problems or a history of liver problems.
- You have kidney problems.
- You have a history of cholelithiasis (gallstones).

You will need to look out for these while you are taking PARMODIA.

If you get a serious side effect, you need to stop taking PARMODIA and talk to your doctor straight away.

- Taking other medicines

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

Remember also those not prescribed by a doctor.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Cyclosporine – a medicine to lower the body's immune reactions
- Rifampicin – a medicine to treat infections
- HMG-CoA reductase inhibitors (Statins): Pravastatin sodium, Simvastatin, Fluvastatin sodium, etc. – medicines to reduce cholesterol
Taking a statin as the same time as PARMODIA may increase the risk of muscle problems.
- Clopidogrel sulfate – a medicine to prevent blood clots
- Clarithromycin or Fluconazole – medicines to treat infections
- HIV protease inhibitors: Ritonavir, etc. – medicines to treat HIV
- Anion exchange resins: Cholestyramine or Colestimate – medicines to reduce cholesterol
- Other medicines or food that induce CYP3A enzyme strongly: Carbamazepine, Phenobarbital, Phenytoin, Foods containing hypericum perforatum (St. John's wort), etc.

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How to use PARMODIA

- How much to use

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

You should have a low fat diet before starting PARMODIA, and should continue dietary control during treatment. Your doctor will check your levels of fat in the blood periodically. If an adequate response has not been achieved, your doctor will consider additional or different treatments.

Adults

The usual adult dose is 0.1 mg twice daily. The dose may be adjusted according to your age and symptoms. The maximum dose is 0.2 mg twice daily.

Elderly

No dose adjustment is necessary.

Since elderly patients often have reduced physiological function, PARMODIA should be carefully used.

Children and Infants

The safety of PARMODIA in low birth weight infants, newborns, infants, and children has not been established. No data are available.

Patients with renal impairment (kidney problems)

PARMODIA should be used with caution in patients with severe kidney problems. A lower starting dose or prolonged dosing intervals should be considered.

The maximum dose is 0.2 mg daily.

Patients with hepatic impairment (liver problems)

PARMODIA should be used with caution in patients with liver problems (mild cirrhosis, etc.) or a

history of liver problems. Dose reduction should be considered as necessary.

Do not take PARMODIA if you have severe liver problems, moderate or severe cirrhosis, or biliary obstruction.

- When to use it

Use as directed by your doctor or pharmacist.

Take the tablet(s) by mouth twice daily in the morning and evening. The tablet(s) can be taken without regard to meals.

- How long to use it

Continue taking PARMODIA for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose at usual time. Do not take a double dose to make up for the dose you missed.

- If you use too much (overdose)

If you have accidentally taken more PARMODIA than you should, tell your doctor or pharmacist or go to the hospital emergency unit at once. You may require medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking PARMODIA.

Tell your doctor immediately if you become pregnant while taking PARMODIA.

Stop taking PARMODIA and see a doctor straight away if you get

unexplained muscle problems (e.g. muscle pain, cramps, or weakness) while taking this medicine.

Your doctor will usually conduct blood tests to check your levels of fat, liver function, etc.

- Things you must not do

Do not stop taking PARMODIA unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PARMODIA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of driving and using machines

No studies of the effects of PARMODIA on a patient's ability to drive, or to measure a reduced capacity to safely use machines have been performed.

Tell your doctor as soon as possible if you experience such effects.

Side effects

Like all medicines, PARMODIA can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

If you have any side effects, talk to your doctor or pharmacist.

- Cholelithiasis (gallstones)
- Diabetes including worsening of diabetes
- Liver function abnormal
- Jaundice
- Increase in AST/GOT or ALT /GPT (liver enzymes)
- Increase in blood creatine phosphokinase (an enzyme mainly found in the muscles)
- Increase in blood myoglobin (a protein found in the muscles)
- Myalgia (muscle pain)

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- Rash, Itching
- Increase in HbA1c (a protein found in red blood cells, with glucose attached)
- Increase in low density lipoprotein (that carries fats)
- Increase in blood uric acid (produced by the breakdown of purines)

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 PARMODIA

- Storage

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. The expiry date refers to the last day of that month.

Do not store above 30°C.

After the tablet is divided, store away from humidity, and use within 4 months.

- Disposal

Any unused medicines or waste material should be disposed of in accordance with local requirements. Ask your pharmacist how to throw away medicines you no longer use.

Product Description

- What it looks like

White, round scored film-coated tablets. The tablet is printed with "Kowa 217" on one side and scored on the other side

- Ingredients

Active ingredient: Pemafibrate

Inactive ingredients

Tablet core: Lactose hydrate, Croscarmellose sodium, Microcrystalline cellulose, Hydroxypropylcellulose, Magnesium stearate

Film coating: Hypromellose, Triethyl citrate, Light anhydrous silicic acid, Titanium oxide, Carnauba wax

- MAL number:

MAL23056003AZ

Manufacturer and Product Registration Holder

- Manufacture

Kowa Company, Ltd.,
Nagoya Factory 18-57,
Hatooka 2-chome,
Kita-ku, Nagoya, Aichi, JAPAN

- Product registration holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
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