PARMODIA® XR Film-coated Tablets

Pemafibrate (0.2 mg, 0.4 mg)

What is in this leaflet

What PARMODIA XR is used for

PARMODIA XR 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 risks 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 XR works

PARMODIA XR contains a medicine called pemafibrate. Pemafibrate activates nuclear receptor (PPARα) 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 XR works or why this medicine has been prescribed to you, ask your doctor.

Before you use PARMODIA XR

- *When you must not use it*

Follow all the 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 XR

- 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 XR. If you are not sure, talk to your doctor or pharmacist before taking PARMODIA XR.

- *Pregnancy and breast-feeding*

Do not take PARMODIA XR if you are pregnant or think that you may be pregnant.
The safety of PARMODIA XR has not been established for use during pregnancy.

You should tell your doctor if you are breast-feeding.
The use of PARMODIA XR should be avoided in breast-feeding women. This medicine may get into milk.
If the use of PARMODIA XR is unavoidable, breast-feeding should be discontinued.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking PARMODIA XR 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 XR.

If you get a serious side effect, you need to stop taking PARMODIA XR 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 at the same time as PARMODIA XR 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 Colestimide – 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.

How to use PARMODIA XR

- *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 XR 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 0.2 mg once daily. The dose may be adjusted according to your age and symptoms. The maximum dose is 0.4 mg daily.

Elderly

No dose adjustment is necessary.

Since elderly patients often have reduced physiological function,

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PARMODIA XR should be carefully used.

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

Patients with renal impairment (kidney problems)
PARMODIA XR should be used with caution in patients with severe kidney problems. When administered, PARMODIA XR should be administered at a dose of 0.2 mg once daily.

Patients with hepatic impairment (liver problems)
PARMODIA XR should be used with caution in patients with liver problems (mild cirrhosis, etc.) or a history of liver problems.

Do not take PARMODIA XR 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 once daily. The tablet(s) can be taken without regard to meals.

- *How long to use it*

Continue taking PARMODIA XR 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 the 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 XR 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 XR.

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

Stop taking PARMODIA XR 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 XR unless advised by your doctor.

Do not chew or crush PARMODIA XR. PARMODIA XR should be swallowed whole.

Do not take any new medicines without consulting your doctor.

Do not give PARMODIA XR 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 XR 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 XR 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 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)
- 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 toMedicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PARMODIA XR

- *Storage*

Keep this medicine out of sight and reaches 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 30ºC.

- *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 help to protect the environment.

Product Description

- *What it looks like*

PARMODIA XR Film-coated Tablets 0.2 mg: Light yellow, round film-coated

PARMODIA® XR Film-coated Tablets

Pemafibrate (0.2 mg, 0.4 mg)

tablet. The tablet is printed with "Kowa XR 0.2" on both sides.

PARMODIA XR Film-coated Tablets 0.4 mg: Light yellow, round film-coated tablet. The tablet is printed with "Kowa XR 0.4" on both sides.

- *Ingredients*
  - Active ingredient
    Pemafibrate

  - Inactive ingredients
    - Microcrystalline cellulose spheres
    - Hydrated silicone dioxide,
    - Hypromellose
    - Methacrylic acid copolymer L
    - Ethylcellulose
    - D-Mannitol
    - Microcrystalline cellulose
    - Crospovidone
    - Hydroxypropylcellulose
    - Magnesium stearate
    - Titanium oxide
    - Triethyl citrate
    - Light anhydrous silicic acid
    - Yellow ferric oxide
    - Carnauba wax

- *MAL number:*

PARMODIA XR Film-coated Tablets 0.2 mg
MALXXXXXXXX

PARMODIA XR Film-coated Tablets 0.4 mg
MALXXXXXXXX

Manufacturer and Product Registration Holder

- *Manufacturer*

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

- *Product Registration Holder*

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