

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pioglitazone Teva 15 mg tablets
Pioglitazone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Teva B.V.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER (FOR CALENDARISED PACKS)

Mon.
Tue.
Wed.
Thu.
Fri.
Sat.
Sun.

Medicinal Product no longer authorised

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Pioglitazone Teva 30 mg tablets
Pioglitazone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 30 mg pioglitazone (as hydrochloride).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

14 tablets
28 tablets
30 tablets
50 tablets
56 tablets
84 tablets
90 tablets
98 tablets
112 tablets
196 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/12/757/011-020

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pioglitazone Teva 30 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pioglitazone Teva 30 mg tablets
Pioglitazone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Teva B.V.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER (FOR CALENDARISED PACKS)

Mon.
Tue.
Wed.
Thu.
Fri.
Sat.
Sun.

Medicinal Product no longer authorised

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Pioglitazone Teva 45 mg tablets
Pioglitazone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 45 mg pioglitazone (as hydrochloride).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

14 tablets
28 tablets
30 tablets
50 tablets
56 tablets
84 tablets
90 tablets
98 tablets
112 tablets
196 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/12/757/021-030

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pioglitazone Teva 45 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pioglitazone Teva 45 mg tablets
Pioglitazone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Teva B.V.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER (FOR CALENDARISED PACKS)

Mon.
Tue.
Wed.
Thu.
Fri.
Sat.
Sun.

Medicinal Product no longer authorised

B. PACKAGE LEAFLET

Medicinal Product no longer authorised

Package leaflet: Information for the user

Pioglitazone Teva 15 mg tablets
Pioglitazone Teva 30 mg tablets
Pioglitazone Teva 45 mg tablets
Pioglitazone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pioglitazone Teva is and what it is used for
2. What you need to know before you take Pioglitazone Teva
3. How to take Pioglitazone Teva
4. Possible side effects
5. How to store Pioglitazone Teva
6. Contents of the pack and other information

1. What Pioglitazone Teva is and what it is used for

Pioglitazone Teva contains pioglitazone. It is an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus in adults, when metformin is not suitable or has failed to work adequately. This is the diabetes that usually develops in adulthood.

Pioglitazone Teva helps control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces. Your doctor will check whether Pioglitazone Teva is working 3 to 6 months after you start taking it.

Pioglitazone Teva may be used on its own in patients who are unable to take metformin, and where treatment with diet and exercise has failed to control blood sugar or may be added to other therapies (such as metformin, sulphonylurea or insulin) which have failed to provide sufficient control of blood sugar.

2. What you need to know before you take Pioglitazone Teva

Do not take Pioglitazone Teva

- if you are allergic to pioglitazone or any of the other ingredients of this medicine (listed in section 6).
- if you have heart failure or have had heart failure in the past.
- if you have liver disease.
- if you have had diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting).
- if you have or have ever had bladder cancer.
- if you have blood in your urine that your doctor has not checked.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pioglitazone Teva (also see section 4)

- if you retain water (fluid retention) or have heart failure problems, in particular if you are over 75 years old. If you take anti-inflammatory medicines which can also cause fluid retention and swelling, you must also tell your doctor.
- if you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye).
- if you have cysts on your ovaries (polycystic ovary syndrome). There may be an increased possibility of becoming pregnant because you may ovulate again when you take Pioglitazone Teva. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- if you have a problem with your liver or heart. Before you start taking Pioglitazone Teva you will have a blood sample taken to check your liver function. This check may be repeated at intervals. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with Pioglitazone Teva and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

If you take Pioglitazone Teva with other medicines for diabetes, it is more likely that your blood sugar could fall below the normal level (hypoglycaemia).

You may also experience a reduction in blood count (anaemia).

Broken bones

A higher number of bone fractures was seen in patients, particularly women taking pioglitazone. Your doctor will take this into account when treating your diabetes.

Children and adolescents

Use in children and adolescents under 18 years is not recommended.

Other medicines and Pioglitazone Teva

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

You can usually continue to take other medicines whilst you are being treated with Pioglitazone Teva. However, certain medicines are especially likely to affect the amount of sugar in your blood:

- gemfibrozil (used to lower cholesterol)
- rifampicin (used to treat tuberculosis and other infections)

Tell your doctor or pharmacist if you are taking any of these. Your blood sugar will be checked, and your dose of Pioglitazone Teva may need to be changed.

Pioglitazone Teva with food and drink

You may take your tablets with or without food. You should swallow the tablets with a glass of water.

Pregnancy and breast-feeding

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

Your doctor will advise you to discontinue this medicine.

Driving and using machines

This medicine will not affect your ability to drive or use machines but take care if you experience abnormal vision.

3. How to take Pioglitazone Teva

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

The usual starting dose is one tablet of 15 mg or of 30 mg of pioglitazone to be taken once daily. Your doctor may increase the dose to a maximum of 45 mg once a day. Your doctor will tell you the dose to take.

If you have the impression that the effect of Pioglitazone Teva is too weak, talk to your doctor.

When Pioglitazone Teva is taken in combination with other medicines used to treat diabetes (such as insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide) your doctor will tell you whether you need to take a smaller dose of your medicines.

Your doctor will ask you to have blood tests periodically during treatment with Pioglitazone Teva. This is to check that your liver is working normally.

If you are following a special diet for diabetes, you should continue with this while you are taking Pioglitazone Teva.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

If you take more Pioglitazone Teva than you should

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately. Your blood sugar could fall below the normal level and can be increased by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice.

If you forget to take Pioglitazone Teva

Take Pioglitazone Teva daily as prescribed. However if you miss a dose, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Pioglitazone Teva

Pioglitazone Teva should be used every day to work properly. If you stop using Pioglitazone Teva, your blood sugar may go up. Talk to your doctor before stopping this treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In particular, patients have experienced the following serious side effects:

Heart failure has been experienced commonly (may affect up to 1 in 10 people) in patients taking pioglitazone in combination with insulin. Symptoms are unusual shortness of breath or rapid increase in weight or localised swelling (oedema). If you experience any of these, especially if you are over the age of 65, seek medical advice straight away.

Bladder cancer has been experienced uncommonly (may affect up to 1 in 100 people) in patients taking pioglitazone. Signs and symptoms include blood in your urine, pain when urinating or a sudden need to urinate. If you experience any of these, talk to your doctor as soon as possible.

Localised swelling (oedema) has also been experienced very commonly (may affect more than 1 in 10 people) in patients taking pioglitazone in combination with insulin. If you experience this side effect, talk to your doctor as soon as possible.

Broken bones have been reported commonly (may affect up to 1 in 10 people) in female patients taking pioglitazone and have also been reported in male patients (frequency cannot be estimated from

the available data) taking pioglitazone. If you experience this side effect, talk to your doctor as soon as possible.

Blurred vision due to swelling (or fluid) at the back of the eye (frequency cannot be estimated from the available data) has also been reported in patients taking pioglitazone. If you experience this symptom for the first time, talk to your doctor as soon as possible. Also, if you already have blurred vision and the symptom gets worse, talk to your doctor as soon as possible.

Allergic reactions have been reported (frequency cannot be estimated from the available data) in patients taking pioglitazone. If you have a serious allergic reaction, including hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing stop taking this medicine and talk to your doctor as soon as possible.

The other side effects that have been experienced by some patients taking pioglitazone are:

common (may affect up to 1 in 10 people)

- respiratory infection
- abnormal vision
- weight gain
- numbness

uncommon (may affect up to 1 in 100 people)

- inflammation of the sinuses (sinusitis)
- difficulty sleeping (insomnia)

not known (frequency cannot be estimated from the available data)

- increase in liver enzymes
- allergic reactions

The other side effects that have been experienced by some patients when pioglitazone is taken with other antidiabetic medicines are:

very common (may affect more than 1 in 10 people)

- decreased blood sugar (hypoglycaemia)

common (may affect up to 1 in 10 people)

- headache
- dizziness
- joint pain
- impotence
- back pain
- shortness of breath
- small reduction in red blood cell count
- flatulence

uncommon (may affect up to 1 in 100 people)

- sugar in urine, proteins in urine
- increase in enzymes
- spinning sensation (vertigo)
- sweating
- tiredness
- increased appetite

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#)

listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pioglitazone Teva

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 and the blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage precautions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pioglitazone Teva contains

- The active substance is pioglitazone.
Each Pioglitazone Teva 15 mg tablet contains 15 mg of pioglitazone (as hydrochloride).
Each Pioglitazone Teva 30 mg tablet contains 30 mg of pioglitazone (as hydrochloride).
Each Pioglitazone Teva 45 mg tablet contains 45 mg of pioglitazone (as hydrochloride).
- The other ingredients are mannitol, carmellose calcium, hydroxypropylcellulose and magnesium stearate.

What Pioglitazone Teva looks like and contents of the pack

- Pioglitazone Teva 15 mg tablets are white to off white, round, convex with the number ‘15’ on one side and ‘TEVA’ on the other side.
- Pioglitazone Teva 30 mg tablets are white to off white, round, convex with the number ‘30’ on one side and ‘TEVA’ on the other side.
- Pioglitazone Teva 45 mg tablets are white to off white, round, convex with the number ‘45’ on one side and ‘TEVA’ on the other side.
- The tablets are supplied in blisters in packs of 14, 28, 30, 50, 56, 84, 90, 98, 112 or 196 tablets.

Not all the pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

Manufacturer:

Teva Pharmaceutical Works Private Limited Company
Pallagi út 13,
4042 Debrecen
Hungary

Pharmachemie B.V.
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The Netherlands

Teva Operations Poland Sp z.o.o.
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Poland

Merckle GmbH
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Germany

Balkanpharma Dupnitsa AD
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Dupnitsa 2600,
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This leaflet was last revised in {MM/YYYY}.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.