

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Arco-Teva 30 mg

Tablets

Each tablet contains:
Etoricoxib 30 mg

Arco-Teva 60 mg

Tablets

Each tablet contains:
Etoricoxib 60 mg

Arco-Teva 90 mg

Tablets

Each tablet contains:
Etoricoxib 90 mg

Arco-Teva 120 mg

Tablets

Each tablet contains:
Etoricoxib 120 mg

For a list of inactive ingredients, refer to section 6.

Read this leaflet carefully in its entirety before using the medicine.

- This leaflet contains concise information about **Arco-Teva**. If you have further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed to treat 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.
- The medicine is not intended for children and adolescents under 16 years of age.

1. WHAT IS ARCO-TEVA AND WHAT IS IT USED FOR?

1.1 What is Arco-Teva?

Therapeutic group: **Arco-Teva** is a medicine from a group of medicines called selective COX-2 inhibitors. These belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

1.2 What is Arco-Teva used for?

Arco-Teva 30 mg helps reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis.

Arco-Teva 60 mg helps reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Arco-Teva 90 mg helps reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from rheumatoid arthritis and ankylosing spondylitis. **Arco-Teva 90 mg** is also used for the short term treatment of moderate pain after dental surgery.

Arco-Teva 120 mg helps reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from gout.

What is osteoarthritis?

Osteoarthritis is a disease of the joints. It is caused by the gradual breakdown of cartilage that cushions the edges of the bones. This causes swelling (inflammation), pain, tenderness, stiffness and disability.

What is rheumatoid arthritis?

Rheumatoid arthritis is a long-term inflammatory disease of the joints. It causes pain, stiffness, swelling and increasing loss of movement in the joints it affects. It may also cause inflammation in other areas of the body.

What is gout?

Gout is a disease of sudden, recurring attacks of very painful inflammation and redness in the joints. It is caused by deposits of mineral crystals in the joints.

What is ankylosing spondylitis?

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

2. BEFORE TAKING ARCO-TEVA

2.1 Do not take Arco-Teva if:

- you are allergic (sensitive) to etoricoxib or any of the other ingredients of this medicine (detailed in section 6)
- you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see "Side Effects", section 4)
- you have a stomach ulcer or bleeding in your stomach or intestines.
- you have a serious liver disease
- you have a serious kidney disease
- you are or could be pregnant or you are breast-feeding (see "Pregnancy, breast-feeding, and fertility", section 2.5)
- you are under 16 years of age
- you have inflammatory bowel disease, such as Crohn's disease, ulcerative colitis, or colitis
- you have high blood pressure that is not controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled)
- you suffer from heart failure (moderate or severe)
- you suffer from ischemic heart disease or peripheral vascular disease (poor blood circulation in the legs or feet due to narrowing of or blocked blood vessels)
- you have had any kind of stroke (including mini-stroke, transient ischemic attack or TIA). Etoricoxib may slightly increase your risk of heart attack and stroke and therefore, patients who have had heart problems or stroke in the past should not take it.

If you think that any of these apply to you, do not take the tablets until you consult with your doctor.

2.2 Special warnings regarding use of Arco-Teva

Before treatment with **Arco-Teva**, tell the doctor if:

- You have a history of stomach bleeding or ulcers.
- You are suffering from dehydration, for example, due to a prolonged bout of vomiting or diarrhea.
- You have swelling due to fluid retention.
- You have a history of heart failure or any other heart disease.
- You have a history of high blood pressure. **Arco-Teva** can increase blood pressure in certain people, especially in high dosages, and your doctor will want to check your blood pressure from time to time.
- You have a history of liver or kidney disease.
- You are being treated for an infection. **Arco-Teva** can mask or hide a fever which is a sign of infection.
- You have diabetes, high cholesterol or are a smoker. These factors can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years of age.

If you are not sure if any of the above apply to you, talk to your doctor before taking **Arco-Teva** to see if this preparation is suitable for you.

Arco-Teva works equally well in young adults and in older patients. If you are over 65 years of age, your doctor will want to look after you properly. No dosage adjustment is necessary for patients over 65 years of age.

2.3 Taking other medicines

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the attending doctor or pharmacist. In particular, if you are taking any of the following medicines, your doctor will want to monitor you to check that your medicines are working properly after starting **Arco-Teva** treatment:

- medicines that thin the blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system, and often used to treat rheumatoid arthritis)
- cyclosporin or tacrolimus (medicines used for suppressing the immune system)
- lithium (a medicine used to treat some types of depression)
- preparations used to treat high blood pressure and heart failure, called ACE inhibitors and angiotensin receptor antagonists, e.g., enalapril, ramipril, losartan and valsartan
- diuretics
- digoxin (a medicine for heart failure and irregular heart rhythm)
- minoxidil (a drug used to treat hypertension)
- salbutamol tablets or oral solution (a medicine for asthma)
- contraceptive pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- aspirin, the risk of stomach ulcers is greater if you take **Arco-Teva** with aspirin.
 - aspirin for prevention of heart attacks or stroke:
Arco-Teva can be taken with low-dosages of aspirin. If you are currently taking low-dosage of aspirin to prevent heart attacks or stroke, do not stop taking aspirin without consulting with your doctor.
 - aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):
do not take aspirin at high-dosage or other anti-inflammatory medicines while taking **Arco-Teva**.

2.4 Taking Arco-Teva with food and drink

Arco-Teva tablets may be taken with or without food. The onset of the effect of **Arco-Teva** may be faster when taken without food.

2.5 Pregnancy, breast-feeding and fertility

Pregnancy

Do not take **Arco-Teva** tablets during pregnancy. If you are pregnant or think you could be pregnant, or if you are planning to become pregnant, do not take the tablets. If you become pregnant, stop taking the tablets and consult your doctor. Consult with your doctor if you are unsure or need more advice.

Breast-feeding

It is not known whether **Arco-Teva** is secreted into breast milk. If you are breast-feeding or planning to breast-feed, consult your doctor before taking **Arco-Teva**. If you are using **Arco-Teva**, do not breast-feed.

Fertility

Arco-Teva is not recommended in women attempting to become pregnant.

2.6 Driving and using machines

Dizziness and sleepiness have been reported in some patients taking **Arco-Teva**.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

2.7 Children and adolescents

Do not give this medicine to children and adolescents under 16 years of age.

3. HOW SHOULD ARCO-TEVA BE USED?

Always use **Arco-Teva** precisely as the doctor has told you. Check with the doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined by the doctor only. **Do not take more than the recommended dose for your condition.** Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain and that you do not take **Arco-Teva** for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially in high dosages.

There are different strengths available for this preparation and your doctor will prescribe the appropriate strength for you according to your illness.

The usually recommended dosage is:

Osteoarthritis

The recommended dosage is 30 mg once a day; can be increased to a maximum of 60 mg once a day, if necessary.

Rheumatoid arthritis

The recommended dosage is 60 mg once a day, can be increased to a maximum of 90 mg once a day, if necessary.

Ankylosing spondylitis

The recommended dosage is 60 mg once a day, can be increased to a maximum of 90 mg once a day, if necessary.

Acute pain conditions

Etoricoxib should be used only for the acute painful period.

Gout

The recommended dosage is 120 mg once a day, which should only be used for the acute painful period, limited to a maximum of 8 days of treatment.

Postoperative dental surgery pain

The recommended dosage is 90 mg once daily, limited to a maximum of 3 treatment days.

Patients with liver problems

- If you have mild liver disease, do not take more than 60 mg once a day.

- If you have moderate liver disease, do not take more than 30 mg once a day.

Do not exceed the recommended dose.

Use in children and adolescents

Do not give **Arco-Teva** to children or adolescents under 16 years of age.

Elderly

No dosage adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

Method of administration

Arco-Teva is intended for oral administration. Take the tablets once a day. **Arco-Teva** can be taken with or without food. Swallow the medicine with a small amount of water.

There is no information regarding crushing/halving/chewing the tablets.

If you take more Arco-Teva than you should

Never take more tablets than the doctor recommended. If you take too many **Arco-Teva** tablets, you should seek medical attention immediately.

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

If you forgot to take Arco-Teva

It is important to take **Arco-Teva** as your doctor has prescribed for you. **If you missed taking a dose**, take the next tablet at the regular time, the following day. Do not take a double dose to make up for the forgotten dose.

Complete the treatment fully as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have any further questions regarding use of the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with all medicines, **Arco-Teva** may cause side effects in some users.

Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

If you develop any of the following signs, stop treatment with Arco-Teva and refer to a doctor immediately (see "Before taking Arco-Teva", section 2):

- shortness of breath, chest pain and ankle swelling that occur or get worse;
- yellowing of the skin and eyes (jaundice) - these are signs of liver problems;
- severe or prolonged stomach pain or black stools;
- an allergic reaction - which can include skin reactions such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing

The following side effects may occur during treatment with **Arco-Teva**:

Very common side effects (affect more than 1 user in 10):

- stomach pain

Common side effects (affect 1 to 10 users in 100):

- dry socket (inflammation and pain after a tooth extraction);
- swelling of the legs and/or feet due to fluid retention (edema);
- dizziness, headache;
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia);
- increased blood pressure;
- wheezing or shortness of breath (bronchospasm);
- constipation, flatulence (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhea, indigestion (dyspepsia)/stomach discomfort, nausea, vomiting, inflammation of the esophagus, mouth ulcers;
- changes in blood tests related to the liver;
- bruising;
- weakness and fatigue, flu-like illness

Uncommon side effects (affect 1 to 10 users in 1,000):

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection;
- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, decreased platelets);
- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention);
- appetite increase or decrease, weight gain;
- anxiety, depression, decrease in sensory acuity;
- seeing, feeling or hearing things that do not exist (hallucinations);
- taste alteration, inability to sleep, numbness or tingling, sleepiness;
- blurred vision, eye irritation and redness;
- ringing in the ears, vertigo (sensation of spinning while standing still);
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack;
- flushing, stroke, mini-stroke (transient ischemic attack), severe rise in blood pressure, inflammation of the blood vessels;
- cough, breathlessness, nose bleed;
- stomach or bowel bloating, changes in bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas;
- swelling of the face, skin rash or itchy skin, redness of the skin;
- muscle cramp/spasm, muscle pain/stiffness;
- high levels of potassium in your blood, changes in blood or urine tests related to your kidney, serious kidney problems;
- chest pain

Rare side effects (affect 1 to 10 users in 10,000):

- angioedema (an allergic reaction accompanied by swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, and may be serious enough to require immediate medical attention)/anaphylactic reactions including shock (a serious allergic reaction that requires immediate medical attention);
- confusion, restlessness;
- liver problems (hepatitis);
- low blood levels of sodium;
- liver failure, yellowing of the skin and/or eyes (jaundice);
- severe skin reactions

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD ARCO-TEVA BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use **Arco-Teva** after the expiry date (exp. date) that is indicated on the package. The expiry date refers to the last day of that month.

Store below 25°C.

Store in the original package to protect from light. Do not discard medicines in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

6.1 What does Arco-Teva contain?

• The active ingredient is etoricoxib. Each film-coated tablet contains 30, 60, 90 or 120 mg of etoricoxib.

• The additional ingredients are:

Core:

Microcrystalline cellulose, Crospovidone (Type A), Povidone (K25), Magnesium stearate.

Film-coating:

Arco-Teva 30 mg

Hypromellose, Titanium dioxide, Talc, Hydroxypropylcellulose, medium chain Triglycerides. Microcrystalline cellulose, Indigo Carmine (Blue 2) Al-lake(E132), Iron oxide red (E172)

Arco-Teva 60 and 120 mg

Hypromellose, Titanium dioxide, Talc, Hydroxypropylcellulose, medium chain Triglycerides. Iron oxide yellow (E172), Indigo Carmine (Blue 2) Al-lake(E132), Brilliant blue (Blue 1) Al-lake(E133), Iron oxide black (E172)

Arco-Teva 90 mg

Hypromellose, Titanium dioxide, Talc, Hydroxypropylcellulose, medium chain Triglycerides.

6.2 What Arco-Teva looks like and the contents of the package

Arco-Teva tablets are available in four strengths:

Arco-Teva 30 mg are round, biconvex, blue, film-coated tablets, with "30" imprinted on one side of the tablet while the other side is plain

Arco-Teva 60 mg are round, biconvex, dark green, film-coated tablets, with "60" imprinted on one side of the tablet while the other side is plain

Arco-Teva 90 mg are round, biconvex, white, film-coated tablets, with "90" imprinted on one side of the tablet while the other side is plain

Arco-Teva 120 mg are round, biconvex, pale green, film-coated tablets, with "120" imprinted on one side of the tablet while the other side is plain

Package sizes:

Arco-Teva 30 mg: packages with 7, 10, 14, 28, 30 tablets in trays.

Arco-Teva 60, 90, 120 mg: packages with 7, 10, 14, 30 tablets in trays.

Not all package sizes may be marketed.

Manufacturer:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva

Registration holder and address:

Abic Marketing Ltd., P.O.B. 8077, Netanya
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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Arco-Teva 30 mg tablets: 160.75.35104
Arco-Teva 60 mg tablets: 160.78.35105
Arco-Teva 90 mg tablets: 160.77.35106
Arco-Teva 120 mg tablets: 160.76.35107

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