

PYCIP FILM COATED TABLETS

Ciprofloxacin hydrochloride (500mg)

What is this in leaflet

1. What PYCIP is used for
2. How it works
3. Before you use PYCIP
4. How to use PYCIP
5. While you are using it
6. Side effects
7. Storage and Disposal of PYCIP
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What PYCIP is used for

PYCIP can be used to treat or prevent certain infections caused by bacteria: Infections of the respiratory tract, urinary tract, gastrointestinal (GI), skin and soft tissues, bones and joints.

Bacteria in the blood (Septicemia), inflammation of the inner wall of the abdomen (peritonitis), infection in patients with reduced immunity.

How PYCIP works

PYCIP contains ciprofloxacin as active ingredient. It belongs to a group of antibiotic called fluoroquinolone.

Antibiotics kill the bacteria or germ which causes infections.

Before you use PYCIP

- When you must not use it

Do not take PYCIP if you have ever had a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

- Before you start to use it

Tell your healthcare provider about all your medical conditions, including if you:

- Have tendon problems
- Have central nervous system problems such as nervousness, extreme emotional disturbance (agitation), trouble falling asleep

(insomnia), fear or worry (anxiety), nightmares or mental emotional disturbance (paranoia).

- You are breast-feeding a baby; pregnant, or trying to become pregnant soon.
- You have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- You have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers- Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).

- You should not take fluoroquinolone antibacterial medicines, including PYCIP, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal and dietary supplements. PYCIP and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- Products that contain caffeine or theophylline (medicine to treat asthma or lungs).
- Duodenal ulcers medicine (eg Sucralfate), antiretroviral medicine (eg didanosine), an antacid, multivitamin, or other product that has magnesium, calcium, aluminum,

iron, or zinc.

- Antiepileptic (anticonvulsants, medicine for the treatment of seizures)
 - Sulfonylurea glyburide (antidiabetic medicines)
 - Immunosuppressant medicine (medicines that dampen down the activity of the body’s immune system) (cyclosporine)
 - The oral anticoagulant (medicines that prevent blood clotting) warfarin or its derivatives.
 - Medication for gout (Probenecid)
 - Medication to treat arthritis and rheumatic condition (Methotrexate)
 - A Non-Steroidal Anti Inflammatory Drug, NSAIDs (usually for the treatment of pain) in combination of very high doses of quinolones.
 - Metoclopramide (medication to treat nausea) Ask your healthcare provider if you are not sure if any of your medicines are listed above.
- Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How to use PYCIP

- How much to use

Your healthcare provider will prescribe a suitable dose for you based on the type and severity of infection that you have. Take PYCIP exactly as prescribed by your healthcare provider.

- When to use it

Take PYCIP as prescribed by your healthcare provider. Swallow the tablet whole. Do not split, crush or chew the tablet. Tell your healthcare provider if you cannot swallow the tablet whole. Drink plenty of fluids while taking PYCIP.

PYCIP FILM COATED TABLETS

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- How long to use it

Do not skip any doses, or stop taking PYCIP even if you begin to feel better, until you finish your prescribed treatment. You have to consult your healthcare provider before stopping.

- If you forget to use it

If you miss a dose of PYCIP, take it as soon as you remember, if it is near the next dose you should skip the missed dose and not double up doses.

- If you use too much (overdose)

If you take too much, call your healthcare provider or get medical help immediately. In the event of acute overdosage, reversible renal toxicity has been reported in some cases.

While you are using it

- Things you must do

Drink more water to maintain your body hydration to prevent the formation of highly concentrated urine. Tell your healthcare provider about side effect occurs while taking ciprofloxacin. Your doctor will decide whether treatment with ciprofloxacin needs to be stopped.

- Things you must not do

PYCIP can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how affects you.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

- Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including PYCIP, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or

potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including PYCIP for the first time.

In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts. If you develop such reactions, stop taking/ using PYCIP and inform your doctor immediately.

Tell your healthcare providers if you have had one of the above effects during or shortly taking a fluoroquinolone-this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

- Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk in

increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids.

Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of PYCIP therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking PYCIP, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

- Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/ or weakness especially in the feet and legs or hands and arms. If this happens, stop taking PYCIP and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side effects

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves- in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

Body as a whole: headache, abdominal pain/discomfort, foot pain, pain, pain in extremities.

Cardiovascular: palpitation (fast heart rate), atrial flutter (abnormality in the beating of the heart), ventricular ectopy (extra heartbeat that originates from the lower chamber of the heart), syncope (fainting), hypertension (high blood pressure)

Central nervous system:

PYCIP FILM COATED TABLETS

Ciprofloxacin hydrochloride (500mg)

restlessness, dizziness, insomnia
(difficulty in sleeping),

nightmares *Gastrointestinal:*

painful oral mucosa, dysphagia

(difficulty in swallowing),

gastrointestinal bleeding

Musculoskeletal: arthralgia (joint

pain) or back pain, joint stiffness,

neck or chest pain

Renal/urogenital: interstitial

nephritis (inflammation of the

kidney in which the interstitial

connective tissue is chiefly

affected)

Respiratory: dyspnea (difficulty

in breathing), epistaxis (nose

bleed), laryngeal or pulmonary

edema (abnormal buildup of fluid

in the lung) *Skin/hypersensitivity:*

allergic reaction, pruritus

(itching), edema of the face, neck,

lips, hyperpigmentation

Special senses: blurred vision,

disturbed vision (change in color

perception, over brightness of

lights), decreased visual acuity,

diplopia (double vision), eye pain,

tinnitus (ringing in the ear), hearing

loss.

If you encounter any other side

effects not mention here, please

refer to your healthcare provider.

Rare: Depression (potentially
leading to thoughts of suicide,
suicide attempts, or completed
suicide), or hallucinations

Very rare: Psychotic reactions
potentially leading to thoughts of
suicide, suicide attempts, or
completed suicide

You may report any side effects or
adverse drug reactions directly to
The National Centre for Adverse
Drug Reaction Monitoring by
visiting the website
np.ra.moh.gov.my (Consumers ->
Reporting ->Reporting Side Effects
to Medicines (ConSERF) or
Vaccines (AEFI)).

Storage and Disposal of PYCIP

- Storage

Protect from light (below 30°C).

Keep PYCIP 500mg and all
medicines out of the reach of children.

The expiry date of this medicinal
product is printed on the box and
blister foil. Do not use this medicinal
product after the expiry date.

- Disposal

Medicines should not be disposed of
via waste water 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

PYCIP 500mg film-coated tablet
appears as white film-coated caplet,
with a fracture line on the side. Blister
packed in PVC/Aluminum blister and
packed in card box (packs of 10x10's)

- Ingredients

- Active ingredient: EachPYCIP
contains Ciprofloxacin
hydrochloride equivalent to
Ciprofloxacin 500mg

- Inactive ingredients:
Pregelatinized starch, Maize
starch, Magnesium stearate,
Sodium Starch Glycolate,
Opadryl White, Titanium
Dioxide

- MAL numbers:

MAL12085065AZ

Manufacturer

PYMEPHARCO JOINT STOCK
COMPANY

(PYMEPHARCO is a subsidiary of
STADA Arzneimittel AG)

166-170 Nguyen Hue Str, Tuy Hoa
City, Phu Yen Province, VietNam

Product Registration Holder

DKSH Malaysia Sdn Bhd,
B-11-01, The Ascent, Paradigm No.1,
Jalan SS7/26A, Kelana Jaya 47301
Petaling Jaya
Selangor Darul Ehsan

Date of revision

18/04/2024

Serial Number:

NPRA(R2/2)240613/1289