

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

REYATAZ 150 mg CAPSULES (atazanavir)

REYATAZ 200 mg CAPSULES (atazanavir)

### READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING

#### REYATAZ:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- REYATAZ has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### WHAT REYATAZ CONTAINS:

REYATAZ capsules contain the equivalent of 150 mg and 200 mg of atazanavir as atazanavir sulphate active ingredient.

The other ingredients are lactose monohydrate, crospovidone, magnesium stearate, gelatin, FD&C Blue #2, and titanium dioxide.

Contains sugar (lactose monohydrate).

#### WHAT REYATAZ IS USED FOR:

REYATAZ is a medicine used in combination with other anti-HIV (antiretroviral) medicines to treat people 6 years of age and older who are infected with the human immuno-

deficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). REYATAZ is a type of anti-HIV medicine called a protease inhibitor. REYATAZ helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply.

#### **BEFORE TAKING REYATAZ:**

##### **Do not take REYATAZ:**

- **If you are allergic to REYATAZ or any of its ingredients.** The active ingredient is atazanavir sulfate. See “**WHAT REYATAZ CONTAINS**” for a complete list of ingredients in REYATAZ. Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.
- **If you are taking certain medicines.** (See “**Taking other Medicines with REYATAZ**”). Serious life-threatening side effects or death may happen. Before you take REYATAZ, tell your healthcare provider about all medicines you are taking or planning to take. These include other prescription and non-prescription medicines, vitamins, and herbal supplements.

##### **Take Special Care with REYATAZ:**

Some people will need special care before or while taking REYATAZ. Tell your doctor or healthcare professional before taking REYATAZ. Make sure your doctor knows:

- If you have liver problems or are infected with the hepatitis B or C virus.
- If you have diabetes.
- If you have haemophilia. **Some patients with haemophilia** have increased bleeding problems with protease inhibitors like REYATAZ.
- If you require haemodialysis.
- If you are taking oral contraceptives (“the PILL”) to prevent pregnancy.

- If you are taking omeprazole or other proton pump inhibitors; or famotidine or other H<sub>2</sub>-receptor antagonists (used to treat diseases related to acid in the stomach).
- If you notice changes in body fat. Redistribution, accumulation, or loss of body fat may occur in patients receiving antiretroviral therapy. This may include an increased amount of fat in the upper back and neck (buffalo hump), breast and around the trunk. Loss of fat from the legs, arms, and face may also occur. The cause and long-term health effects of these conditions are not known at this time.

Kidney stones have been reported in patients taking REYATAZ. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate), please inform your doctor immediately.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Current antiretroviral therapy, including REYATAZ, does not prevent the risk of transmission of HIV infection (AIDS) to others through sexual contact or blood contamination. Appropriate precautions should continue to be employed.

Hyperbilirubinaemia (an increase in the level of bilirubin in the blood) has occurred in patients receiving REYATAZ. These signs may be a mild yellowing of the skin or eyes. If you notice any of these symptoms please inform your doctor.

Serious skin rash, including Stevens-Johnson syndrome, has been reported in patients taking REYATAZ. If you develop a rash, inform your doctor immediately.

If you notice a change in the way your heart beats (heart rhythm changes), please inform your doctor.

**Taking REYATAZ with food and drink:**

Always take REYATAZ with food (a meal or snack) as this helps the body absorb the medicine.

**Pregnancy and Breastfeeding:**

**If you are pregnant or breastfeeding your baby while taking REYATAZ, please consult your doctor, pharmacist or other healthcare professional for advice.**

**Mothers who are breastfeeding should not take REYATAZ.**

**Tell your healthcare provider:**

- If you are breastfeeding or plan to breastfeed your baby.
- If you are taking REYATAZ, you should not breastfeed your baby.

**Driving and using machinery:**

There have been reports of adverse nervous system side effects that may influence your ability to drive or use machines. If you feel dizzy or light headed, contact your doctor immediately.

**Important information about some of the ingredients of REYATAZ:**

REYATAZ contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take REYATAZ.

**Taking other medicines with REYATAZ:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

- **Do not take REYATAZ if you take the following medicines. Serious life-threatening side effects or death may happen.** Ergot containing medicines: such as dihydroergotamine, ergonovine, ergotamine, methylergonovine, triazolam, midazolam, pimozide, cisapride.
- **Do not take the following medicines with REYATAZ because of possible serious side effects.** Irinotecan, indinavir, lovastatin, simvastatin, alfuzosin, sildenafil.
- **Do not take the following medicines with REYATAZ because they may lower the amount of REYATAZ in your blood.** Rifampicin, St. John's Wort (*Hypericum perforatum*), nevirapine.
- **Do not take the following medicine if you are taking REYATAZ and ritonavir:** Voriconazole, quinidine.

**The following medicines may require your healthcare provider to monitor your therapy more closely (for some medicines a change in the dose or dose schedule may be needed).** REYATAZ may increase the chance of serious side effects when taken with tadalafil, vardenafil, atorvastatin, amiodarone, lidocaine, quinidine, bepridil, warfarin, amitriptyline, trimipramine, imipramine, ciclosporin, sirolimus, tacrolimus, trazodone, fluticasone propionate.

- **The following medicines may require a change in dose or dose schedule of either REYATAZ or the other medicines:** Saquinavir, ritonavir, efavirenz, antacids or buffered medicines, didanosine, tenofovir, rifabutin, diltiazem, verapamil, clarithromycin, nizatidine, famotidine, cimetidine, ranitidine, buprenorphine.

**Talk to your healthcare provider about choosing an effective method of contraception.** REYATAZ may affect the safety and effectiveness of hormonal contraceptives such as birth control pills or the contraceptive patch. Hormonal contraceptives do not prevent the spread of HIV to others.

#### **HOW TO TAKE REYATAZ:**

Always take REYATAZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- **Take REYATAZ once every day as instructed by your healthcare provider.** Your healthcare provider will prescribe the amount of REYATAZ that is right for you.
- Your dose will depend on your liver function and on the other anti-HIV medicines that you are taking. REYATAZ is always used with other anti-HIV medicines. If you are taking REYATAZ with efavirenz or with tenofovir, you should also be taking ritonavir.

- **Always take REYATAZ with food** (a meal or snack) to help it work better. Swallow the capsules whole. Do not open the capsules. Try to take REYATAZ at the same time each day.
- **If you are taking antacids or Videx® (didanosine) chewable/ dispersable buffered tablets**, take REYATAZ 2 hours before or 1 hour after these medicines.
- **If you are taking medicines for indigestion, heartburn, or ulcers such as nizatidine, famotidine, cimetidine or ranitidine**, talk to your healthcare provider.

**If you take more REYATAZ than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take a dose of REYATAZ:**

If you miss a dose of REYATAZ, take it as soon as possible and then take your next scheduled dose at its regular time. If, however, it is within 6 hours of your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose. **It is important that you do not miss any doses of REYATAZ or your other anti-HIV medicines.**

**Effects when treatment with REYATAZ is stopped:**

- **Do not change your dose or stop taking REYATAZ without first talking with your healthcare provider.** It is important to stay under a healthcare provider's care while taking REYATAZ.
- Do not share medicines prescribed for you with others.
- **When your supply of REYATAZ starts to run low**, get more from your healthcare provider or pharmacy. It is important not to run out of REYATAZ. The

amount of HIV in your blood may increase if the medicine is stopped for even a short time.

**POSSIBLE SIDE EFFECTS:**

REYATAZ can have side effects.

Not all side effects reported for REYATAZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking REYATAZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

**Rash** (redness and itching) sometimes occurs in patients taking REYATAZ, most often in the first few weeks after the medicine is started.

- **Severe rash:** Rash may develop in association with other symptoms which could be serious and potentially cause death.

**If you develop a rash with any of the following symptoms stop using REYATAZ and call your healthcare provider right away:**

- shortness of breath
- general ill feeling or “flu-like” symptoms
- fever
- muscle or joint aches
- conjunctivitis (red or inflamed eyes, like “pink eye”)
- blisters
- mouth sores
- swelling of your face

- **Yellowing of the skin or eyes.** These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Although these effects may not be damaging to your liver, skin or eyes, call your healthcare provider promptly if your skin or the white part of your eyes turn yellow.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to REYATAZ. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- **A change in the way your heart beats (heart rhythm change).** If you experience dizziness or light-headedness, these could be symptoms of a heart problem.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- **Diabetes and high blood sugar (hyperglycaemia)** sometimes happen in patients taking protease inhibitor medicines like REYATAZ. Some patients had diabetes before taking protease inhibitors while others did not. Some patients may need changes in their diabetes medicine.
- **If you have liver disease** including hepatitis B or C, your liver disease may worsen when you take anti-HIV medicines like REYATAZ.

Other frequent side effects of REYATAZ may include:

- headache,
- nausea,
- abdominal pain (stomach pains),
- vomiting,
- diarrhoea,
- tiredness.

Other less frequent side effects of REYATAZ may include:

- fever,
- dizziness,
- trouble sleeping,
- numbness, tingling or burning of hands or feet,
- dry mouth,
- flatulence or wind,
- loss of appetite,
- kidney pain,
- depression,
- muscle pain,
- breast enlargement in men.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **STORING AND DISPOSING OF REYATAZ:**

- Store all medicines out of reach of children.
- Store REYATAZ capsules at or below 25 °C.
- Do not store this medicine in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Keep your medicine in a tightly closed container.
- Do not use REYATAZ capsules after the expiry date.
- Do not share medicines prescribed for you with others.

#### **PRESENTATION OF REYATAZ:**

REYATAZ capsules are packed in white HDPE (high density polyethylene) bottles with child resistant, white closures with an aluminium induction seal, in sizes of 60's.

**IDENTIFICATION OF REYATAZ:**

REYATAZ 150 mg capsules are size #1, two-piece, blue opaque cap and powder blue opaque body, hard gelatin capsule printed in white with "BMS", "150 mg" and in blue with "3624". The contents consist of white to light yellow granules which may appear as powder.

REYATAZ 200 mg capsules are size #0, two-piece, blue opaque cap and body, hard gelatin capsule printed in white with "BMS", "200 mg" and "3631". The contents consist of white to light yellow granules which may appear as powder.

**REGISTRATION NUMBERS:**

REYATAZ 150 mg CAPSULES: A39/20.2.8/0088

REYATAZ 200 mg CAPSULES: A39/20.2.8/0089

**THE NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:**

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