

## Package leaflet: Information for the patient

<b>Exviera® 250 mg film-coated tablets</b>
Dasabuvir

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**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**

- What Exviera is and what it is used for
- What you need to know before you take Exviera
- How to take Exviera
- Possible side effects
- How to store Exviera
- Contents of the pack and other information

### 1. What Exviera is and what it is used for

Exviera is an antiviral medicine used to treat adults with chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus). It contains the active substance dasabuvir.

Exviera works by stopping the hepatitis C virus from multiplying and infecting new cells, thus clearing the virus from your blood over a period of time.

Exviera tablets do not work on their own. They are always taken with another antiviral medicine containing ombitasvir/paritaprevir/ritonavir. Some patients may also take an antiviral medicine called ribavirin. Your doctor will talk with you about which of these medicines to take with Exviera.

It is very important that you also read the package leaflets for the other antiviral medicines that you take with Exviera. If you have any questions about your medicines, please ask your doctor or pharmacist.

### 2. What you need to know before you take Exviera

**Do not take Exviera:**

- If you are allergic to dasabuvir or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver problems other than hepatitis C.
- If you are taking any of the medicines listed in the following table. This is because serious or life-threatening effects can occur when Exviera and ombitasvir/paritaprevir/ritonavir are taken with these medicines. These medicines can affect the way Exviera and ombitasvir/paritaprevir/ritonavir work and Exviera and ombitasvir/paritaprevir/ritonavir can affect the way these other medicines work.

<b>Medicines you must not take with Exviera</b>	
<b>Medicine or active substance</b>	<b>Purpose of the medicine</b>
carbamazepine, phenytoin, phenobarbital	for epilepsy
efavirenz, etravirine, nevirapine	for HIV infection
enzalutamide	for prostate cancer
ethinylestradiol containing medicines such as those contained in most contraceptive pills and vaginal rings used for contraception	for contraception
gemfibrozil	to lower cholesterol and other fats in the blood
mitotane	for some tumours of the adrenal glands
rifampicin	for bacterial infections
St. John’s Wort ( <i>hypericum perforatum</i> )	a herbal medicine for anxiety and mild depression. This medicine is available without a prescription

Do not take Exviera if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Exviera.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Exviera if you have liver disease other than hepatitis C.

When taking Exviera and ombitasvir/paritaprevir/ritonavir, tell your doctor if you have the following symptoms as they may be a sign of worsening liver problems:

- Feel sick (nauseous), are sick (vomit) or lose your appetite.
- Notice yellowing of your skin or eyes.
- Your urine is darker than normal.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Exviera.

**Blood tests**

Your doctor will test your blood before, during and after your treatment with Exviera. This is so that your doctor can:

- Decide what other medicines you should take with Exviera and for how long.
- Confirm if your treatment has worked and if you are free of the hepatitis C virus.
- Check for side effects of Exviera or other antiviral medicines your doctor has prescribed for you to use with Exviera (such as “ombitasvir/paritaprevir/ritonavir” and “ribavirin”).

**Children and adolescents**

Do not give Exviera to children and adolescents under 18 years of age. The use of Exviera in children and adolescents has not yet been studied.

**Other medicines and Exviera**

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

There are some medicines you **must not take** with Exviera - see the previous table “Medicines you must not take with Exviera”.

**Tell your doctor or pharmacist** before taking Exviera, if you are taking any of the medicines in the table below. The doctor may need to change your dose of these medicines. Tell your doctor or pharmacist before taking Exviera if you are also using hormonal contraceptives. See the section on contraception below.

<b>Medicines you must tell your doctor about before taking Exviera</b>	
<b>Medicine or active substance</b>	<b>Purpose of the medicine</b>
alprazolam	for anxiety, panic attacks and trouble sleeping
ciclosporin, tacrolimus	to suppress the immune system
dabigatran, warfarin	to thin the blood
deferasirox	to help reduce iron levels in the blood
digoxin, amlodipine	for heart problems or high blood pressure
furosemide	for the build-up of too much fluid in the body
imatinib	for the treatment of some cancers of the blood
levothyroxine	for thyroid problems
darunavir/ritonavir, atazanavir/ritonavir, rilpivirine	for HIV infection
omeprazole, lansoprazole, esomeprazole	for stomach ulcers and other stomach problems
rosuvastatin, pravastatin, fluvastatin, pitavastatin	to lower blood cholesterol
s-mephenytoin	for epilepsy
teriflunomide	for multiple sclerosis
sulfasalazine	to treat and manage inflammatory bowel disease or to treat rheumatoid arthritis

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Exviera.

**Pregnancy**

Women must not become pregnant while they or their partners are being treated with Exviera and ombitasvir/paritaprevir/ritonavir with ribavirin. This is because ribavirin can cause birth defects or the death of your unborn baby.

- Do not start treatment if you are pregnant.
- Do not become pregnant during treatment.
- If you or your partner become pregnant during treatment or in the 6 months after treatment, contact your doctor straight away.

Ask your doctor or pharmacist for advice if you are taking Exviera and ombitasvir/paritaprevir/ritonavir with or without ribavirin, and you or your partner are planning to become pregnant.

Read the “Pregnancy” sections of the package leaflets for the other antiviral medicines that you take with Exviera (such as “ombitasvir/paritaprevir/ritonavir” and “ribavirin”). It is important that both men and women read the information.

**Contraception**

If you are taking Exviera and ombitasvir/paritaprevir/ritonavir with ribavirin, you or your partner must use an effective method of contraception during treatment and for 6 months after treatment is finished. Ask your doctor about the best contraception for you.

Talk to your doctor before taking Exviera and ombitasvir/paritaprevir/ritonavir if you are using a contraceptive medicine that contains ethinylestradiol. Your doctor will ask you to stop and change to a different type of contraceptive medicine during your treatment with Exviera.

Read the “Contraception” section of the package leaflets for the other anti-viral medicines that you take with Exviera (such as “ ombitasvir/paritaprevir/ritonavir” and “ribavirin”). It is important that both men and women read the information.

**Breastfeeding**

You should not breastfeed during treatment with Exviera. It is not known whether the active substance in Exviera (dasabuvir), passes into breast milk.

**Driving and using machines**

Some patients have reported feeling very tired when taking Exviera with other medicines for their hepatitis C infection. If you feel tired, do not drive or use any machines.

**Exviera contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Exviera

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

Exviera tablets do not work on their own. They are always taken with other antiviral medicines such as ombitasvir/paritaprevir/ritonavir. Your doctor may also give you an antiviral medicine called ribavirin.

**How much to take**

The recommended dose is one tablet, twice a day. Take one tablet in the morning and one tablet in the evening.

**How to take**

- Take the tablets with food. The type of food is not important.
- Swallow the tablets whole.
- Do not chew, crush or break the tablets as they may have a bitter taste.

**How long to take Exviera for**

You will take Exviera for either 12 or 24 weeks. Your doctor will tell you how long your treatment will last. Do not stop taking Exviera unless your doctor tells you to. It is very important that you complete the full course of treatment. This will give the medicines the best chance to clear the hepatitis C virus infection.

**If you take more Exviera than you should**

If you accidentally take more than the recommended dose, you should contact your doctor or go to the nearest hospital straight away. Keep the medicine pack with you so you can easily describe what you have taken.

**If you forget to take Exviera**

It is important not to miss a dose of this medicine. If you do miss a dose and it is:

- More than 6 hours** until your next dose - take the missed dose with food as soon as possible.
- Less than 6 hours** until your next dose - do not take the missed dose, take your next dose as usual with food. Do not take a double dose to make up for a forgotten dose.

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.

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Side effects when taking Exviera with ombitasvir/paritaprevir/ritonavir:**
**Common:** may affect up to 1 in 10 people

- Itching

**Side effects when taking Exviera and ombitasvir/paritaprevir/ritonavir with ribavirin:**
**Very common:** may affect more than 1 in 10 people

- Feeling very tired (fatigue)
- Feeling sick (nausea)
- Itching
- Trouble sleeping (insomnia)
- Feeling weak or lack of energy (asthenia).

**Common:** may affect up to 1 in 10 people

- Anaemia (low number of red blood cells).

**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. Healthcare professionals are asked to report any suspected adverse reactions via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

**In Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd​a.gov.sa
- Website: www.sfd​a.gov.sa/npc

By reporting side effects, you can help provide more information on the safety of this medicine.

**For rest of the countries:**

**Bahrain, United Arab Emirates, Yemen, Kuwait, Oman, Qatar:**

- Fax: +9714 424 1313
- Email: pv.gulf@abbvie.com

**Iraq, Jordan, Lebanon, Syria, Iran:**

- Hotline: +961 70122946
- Email: Pharmacovigilance\_levant@abbvie.com

### 5. How to store Exviera

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton after ‘EXP’. The expiry date refers to the last day of that month.

Store below 30°C.

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 to protect the environment.

### 6. Contents of the pack and other information

**What Exviera contains**

- Each tablet contains 250 mg of dasabuvir (as sodium monohydrate).
- The other ingredients are:
  - Tablet core: microcrystalline cellulose (E460(i)), lactose monohydrate, copovidone, croscarmellose sodium, colloidal anhydrous silica (E551), magnesium stearate (E470b).
  - Tablet film-coating: polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol 3350, talc (E553b), iron oxide yellow (E172), iron oxide red (E172) and iron oxide black (E172).

**What Exviera looks like and contents of the pack**

Exviera tablets are beige, ovaloid film-coated tablets, of dimensions of 14.0 mm x 8.0 mm, marked with “AV2”. Exviera tablets are packed into foil blisters containing 2 tablets. Each carton contains 56 tablets (multipack carton containing 4 inner cartons of 14 tablets).

**Marketing Authorisation Holder**

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**Manufactured by:**

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Sligo, Ireland

**Packaged and Released by:**
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Germany

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<p>Council of Arab Health Ministers</p>
<p><b>This is a Medicament</b></p> <ul style="list-style-type: none"><li>Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.</li> <li>Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.</li> <li>The doctor and the pharmacist are the experts in medicines, their benefits and risks.</li> <li>Do not by yourself interrupt the period of treatment prescribed for you.</li> <li>Do not repeat the same prescription without consulting your doctor.</li> <li>Keep all medicaments out of reach of children.</li></ul>
<p>Council of Arab Health Ministers Union of Arab Pharmacists</p>