

SCHEDULING STATUS: **S4**



Synjardy® 5/500 mg film-coated tablets
Synjardy® 5/850 mg film-coated tablets
Synjardy® 5/1000 mg film-coated tablets
Synjardy® 12,5/500 mg film-coated tablets
Synjardy® 12,5/850 mg film-coated tablets
Synjardy® 12,5/1000 mg film-coated tablets
empagliflozin/metformin hydrochloride
Sugar free

Read all of this leaflet carefully before you start taking SYNJARDY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SYNJARDY 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 is in this leaflet

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

Do not take SYNJARDY if you have 'type 1' diabetes.

SYNJARDY is not used to control body weight.

There have been reports of 'metabolic acidosis' or 'ketoacidosis' in people taking SYNJARDY, which is life threatening and needs to be treated in hospital.

If you have any symptoms of metabolic acidosis such as feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, you must immediately contact a doctor or the nearest hospital in order to be assessed for metabolic acidosis, even if your blood glucose level is below 11 mmol/L.

Please refer also to 'Warnings and precautions'.

1. What SYNJARDY is and what it is used for

SYNJARDY is used to lower blood sugar levels in patients with type 2 diabetes mellitus.

SYNJARDY contains two different active ingredients:

- empagliflozin, which belongs to a group of medicines called SGLT2 (sodium-glucose co-transporter 2) inhibitors, and
- metformin, which belongs to a class of medicines called biguanides.

Both medicines work together to control blood sugar levels in patients with type 2 diabetes mellitus by increasing the amount of glucose expelled in urine and lowering the amount of sugar made by your body.

It may be used when diet plus exercise do not provide adequate blood sugar level control either:

- alone as a single medicine, or
- in combination with certain other anti-diabetic medicines such as:
 - sulphonylureas
 - pioglitazone
 - insulin
 - linagliptin.

If you have type 2 diabetes mellitus and cardiovascular disease, SYNJARDY can be used to reduce your risk of dying from your cardiovascular disease or being hospitalised for heart failure.

Type 2 diabetes develops if the body does not make enough insulin, or if the insulin that your body makes does not work as well as it should.

Insulin is a substance which helps to lower the level of sugar in your blood, especially after meals.

When the level of sugar builds up in your blood, this can cause damage to the body's cells and lead to serious problems with your heart, eyes, circulation or kidneys.

Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and foot amputation.

Along with diet and exercise, SYNJARDY helps lower your blood sugar.

Your doctor may have prescribed SYNJARDY to replace the anti-diabetic medicine(s) you are currently taking. It is important that you continue to follow the diet and/or exercises recommended for you while you are on treatment with SYNJARDY.

2. What you need to know before you take SYNJARDY

Do not take SYNJARDY

- if you are hypersensitive (allergic) to empagliflozin, metformin or any of the other ingredients of SYNJARDY (listed in Section 6)
- if you have type 1 diabetes mellitus
- if you have any type of metabolic acidosis such as lactic acidosis, or diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- if you have had a diabetic pre-coma
- if you have severe problems with your kidneys
- if you have problems with your liver
- if you have a severe infection
- if you are dehydrated
- if you are treated for acute heart failure or have recently had a heart attack
- if you have severe problems with your circulation (such as shock)

- if you have severe breathing difficulties
- if you have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- if you have significant blood loss
- if you have gangrene
- if you have inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting
- if you drink excessive alcohol (all the time or 'binge' drinking)
- if you are pregnant or are breastfeeding your baby.

Talk to your doctor about when to stop taking SYNJARDY and when to start taking it again if you:

- are going to have an X-ray where you will be injected with an iodinated contrast (dye)
- are planning to have surgery (including where the use of insulin is essential).

Warnings and precautions

Before you start to take SYNJARDY

- Discard any other medicines containing metformin or empagliflozin that your doctor might have prescribed to you in the past and that you may still have in your possession.
SYNJARDY contains empagliflozin and metformin. If you have more than one metformin-containing medicine in your possession you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.
Accidental metformin overdosing is a significant safety risk.
Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin.
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.
- Tell your doctor if you have type 1 diabetes, a condition where your body does not produce insulin.
SYNJARDY should not be used to treat type 1 diabetes.
- Tell your doctor if you are sick, have diarrhoea or fever, or if you are not able to eat or drink.
These conditions can cause dehydration. Your doctor may ask you to stop taking SYNJARDY until you recover to prevent loss of too much body fluid.
- Tell your doctor if you have a serious infection of the kidney or the urinary tract with fever.
Your doctor may ask you to stop taking SYNJARDY until you have recovered.
- Tell your doctor if you have heart problems, history of low blood pressure, or are 75 years of age or older.
Increased passing of urine due to the medicine may affect fluid balance in your body and increase your risk of dehydration.
- Tell your doctor if you are 85 years of age or older.
You should not start taking SYNJARDY if you are over 85 years of age.

If you have not told your doctor about any of the above, tell him/her before you start taking SYNJARDY.

While you are taking SYNJARDY

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SYNJARDY.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking SYNJARDY.
- Talk to your doctor about when to stop taking SYNJARDY and when to start taking it again if you are about to have surgery or an examination such as an X-ray or scan requiring an injection of iodinated contrast (dye).
- If you become pregnant while taking SYNJARDY, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking SYNJARDY. It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may want to perform blood tests to check your kidneys and vitamin B12 levels while you are taking SYNJARDY.
- Follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise. Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor while taking SYNJARDY.
- Make sure you check your blood glucose regularly.
This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.
- Check your feet regularly and see your doctor if you notice any problems. Follow any other advice regarding foot care given by your doctor.
- Tell your doctor if you become ill or dehydrated, or experience stress, injury, fever, infection, or need surgery.
Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis or diabetic ketoacidosis. During these times, your doctor may temporarily replace SYNJARDY with insulin.
- Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

Hypoglycaemia:

SYNJARDY does not normally cause hypoglycaemia on its own, although you may experience it if you take SYNJARDY with certain other medicines or if your calorie intake is deficient or if you are drinking alcohol.

Signs of hypoglycaemia may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

At the first signs of hypoglycaemia, you need to raise your blood glucose quickly.

You can do this by taking one of the following:

- sweets or candy containing sugar e.g. 5 - 7 jellybeans

- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2 - 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Hyperglycaemia:

If you notice the return of any signs of hyperglycaemia, contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less SYNJARDY than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Children and adolescents

Do not give SYNJARDY to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years has not been established.

Other medicines and SYNJARDY

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and SYNJARDY may interfere with each other. These include:

- an antibiotic medicine used to treat certain infections such as tuberculosis (rifampicin).
- a medicine used to treat reflux and ulcers (cimetidine).
- medicines used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids).
- specific medicines for the treatment of high blood pressure (ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, beta-blockers).
- medicines used to prevent blood clots, such as warfarin.
- medicines which increase urine production (diuretics).
- some medicines used to treat asthma (salbutamol or terbutaline).
- medicines used to relieve pain, swelling and other symptoms of inflammation (NSAIDs (non-steroidal anti-inflammatory drugs), such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam and selective COX II inhibitors).
- iodinated contrast agents (which you may receive while having an X-ray).
- alcohol-containing medicines.
- a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits) (tetracosactrin).
- a medicine used to treat endometriosis (danazol).
- a medicine used to treat schizophrenia and other mental illnesses (chlorpromazine).
- a medicine used to treat and prevent mood disorders (lithium).
- medicines used in the treatment of HIV and chronic hepatitis C infections (dolutegravir, daclatasvir).
- medicines used in the treatment of certain cancers (crizotinib, olaparib, vandetanib).

- medicines used to control fits (seizures), chronic pain or glaucoma (topiramate, zonisamide, acetazolamide, dichlorphenamide).

These medicines may be affected by SYNJARDY or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking SYNJARDY.

SYNJARDY with food and drink and alcohol

Take SYNJARDY during or after meals. This will lessen the chance of a stomach upset. Avoid excessive alcohol intake while taking SYNJARDY since this may increase the risk of lactic acidosis (see Section 4).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking SYNJARDY.

Do not take SYNJARDY if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

If you are intending to become pregnant or are pregnant talk to your doctor about alternative medication to control your blood glucose level. It is important your blood glucose levels are as close to normal as possible at this time.

Do not breastfeed your baby if you are taking SYNJARDY.

Both component medicines are excreted in milk.

Driving and using machines

Be careful driving or operating machinery until you know how SYNJARDY affects you.

When taken with other anti-diabetic medicines, such as sulphonylurea or insulin, your risk of getting low blood sugar is higher.

This may cause dizziness, light-headedness, tiredness, drowsiness. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when doing any of the following things, which may increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise.

SYNJARDY contains ingredients as described in Section 6 below.

It is sugar free.

3. How to take SYNJARDY

Do not share medicines prescribed for you with any other person.

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

The usual dose is one SYNJARDY tablet twice daily.

Swallow the tablet whole with a full glass of water during or after meals. This will lessen the chance of a stomach upset.

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It is important that you take SYNJARDY every day.

Your doctor will tell you how long your treatment with SYNJARDY will last. Do not stop treatment early because your blood sugar levels may increase if you stop taking SYNJARDY. SYNJARDY helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you have the impression that the effect of SYNJARDY is too strong, or too weak, tell your doctor or pharmacist.

If you take more SYNJARDY than you should

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

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you forget to take SYNJARDY

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you stop taking SYNJARDY

Do not stop taking SYNJARDY or lower the dosage without checking with your doctor.

4. Possible side effects

SYNJARDY can have side effects.

Not all side effects reported for SYNJARDY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SYNJARDY, please consult your healthcare provider for advice.

Metformin, one of the active substances in SYNJARDY can cause a serious side effect called lactic acidosis.

This is a medical emergency that can cause death. It is caused by build-up of lactic acid in your blood.

Stop taking SYNJARDY if you get any of the following symptoms of lactic acidosis and go to the casualty department at your nearest hospital immediately:

- feeling cold (especially in your arms and legs)
- feeling very weak, tired
- feeling light-headed, dizzy
- severe nausea or vomiting
- feeling uncomfortable
- muscle pain
- drowsiness
- abdominal pain
- unexplained weight loss
- irregular heartbeat
- rapid or difficult breathing.

The above list includes very serious side effects. 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 symptoms of diabetic ketoacidosis such as:

- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst
- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

Empagliflozin, one of the active substances in SYNJARDY can cause a serious side effect called diabetic ketoacidosis.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following which may be symptoms of an allergic reaction:

- sudden onset of hives, itching or skin rash
- swelling of the face, lips or tongue or other parts of the body
- shortness of breath
- wheezing or difficulty breathing.

Tell your doctor immediately if you experience pain or tenderness, itching, swelling in the genital or back passage area, fever or are generally feeling unwell.

These may be symptoms of a serious and life threatening infection called Fournier's gangrene. Your doctor may tell you to stop taking SYNJARDY.

Tell your doctor immediately if you experience swelling of the penis that makes it difficult to pull back the skin around the tip of the penis (uncircumcised men).

Tell your doctor immediately if you notice any of the symptoms of low blood sugar such as:

- sweating
- weakness
- hunger
- dizziness

- trembling
- headache
- flushing or paleness
- numbness
- a fast pounding heartbeat.

Low blood sugar may occur in patients who already take another medicine to treat diabetes, such as a sulphonylurea or insulin. The dose of your sulphonylurea or insulin may need to be reduced while taking SYNJARDY.

Tell your doctor as soon as possible if you notice any of the following:

- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis, or mid-back pain
- straining or pain when passing urine
- unusual thirst
- light-headedness, or dizziness upon standing
- fainting or loss of consciousness.

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- genital burning, redness, pain and discharge which may be signs of a genital yeast infection
- passing more urine than normal
- itching
- loss of appetite
- loss of taste
- thirst
- diarrhoea or stomach-ache
- feeling sick (nausea), vomiting
- constipation.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If you take SYNJARDY, you may be at a greater risk of genital infections and urinary tract infections.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Side effects can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingenelheim.com.

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

5. How to store SYNJARDY

Store at or below 30 °C.

Store all medicines out of reach of children.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Do not store SYNJARDY or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Do not take SYNJARDY after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SYNJARDY contains

The active substances are empagliflozin and metformin hydrochloride.

- Each SYNJARDY 5/500 mg tablet contains 5 mg empagliflozin and 500 mg metformin hydrochloride.
- Each SYNJARDY 5/850 mg tablet contains 5 mg empagliflozin and 850 mg metformin hydrochloride.
- Each SYNJARDY 5/1000 mg tablet contains 5 mg empagliflozin and 1 000 mg metformin hydrochloride.
- Each SYNJARDY 12,5/500 mg tablet contains 12,5 mg empagliflozin and 500 mg metformin hydrochloride.
- Each SYNJARDY 12,5/850 mg tablet contains 12,5 mg empagliflozin and 850 mg metformin hydrochloride.
- Each SYNJARDY 12,5/1000 mg tablet contains 12,5 mg empagliflozin and 1 000 mg metformin hydrochloride.

The other ingredients are:

colloidal anhydrous silica, copovidone, hypromellose, iron oxide yellow (5/500 mg, 5/850 mg, 5/1000 mg tablets), iron oxide black (12,5/500 mg, 12,5/850 mg, 12,5/1000 mg tablets), iron oxide red (12,5/500 mg, 12,5/850 mg, 12,5/1000 mg tablets), magnesium stearate, macrogol 400, maize starch, talc, titanium dioxide.

SYNJARDY does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What SYNJARDY looks like and contents of the pack

- SYNJARDY 5/500 mg tablets are orange yellow, oval, biconvex film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol and 'S5', the other side is debossed with '500'.
- SYNJARDY 5/850 mg tablets are yellowish white, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and 'S5', the other side is debossed with '850'.
- SYNJARDY 5/1000 mg tablets are brownish yellow, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and 'S5', the other side is debossed with '1000'.

- SYNJARDY 12,5/500 mg tablets are pale brownish purple, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and 'S12', the other side is debossed with '500'.
- SYNJARDY 12,5/850 mg tablets are pinkish white, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and 'S12', the other side is debossed with '850'.
- SYNJARDY 12,5/1000 mg tablets are dark brownish purple, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and 'S12', the other side is debossed with '1000'.

SYNJARDY is available in white PVC/PCTFE/Aluminium blister packs containing 60 film-coated tablets.

Holder of Certificate of Registration

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