PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BYETTA 5 µg (microgram) solution for injection

BYETTA 10 µg (microgram) solution for injection

Exenatide

Metacresol 2.20 mg/mL as a preservative

Contains sugar: mannitol 43.0 mg/mL

Read all of this leaflet carefully before you start taking BYETTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BYETTA 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 BYETTA is and what it is used for
2. What you need to know before you use BYETTA
3. How to use BYETTA
4. Possible side effects
5. How to store BYETTA
6. Contents of the pack and other information

1. What BYETTA is and what it is used for

- BYETTA is an injectable medicine used to improve blood sugar control in adults with type 2 (non-insulin dependent) diabetes mellitus.
- BYETTA is used with other anti-diabetic medicines called metformin or sulphonylureas or both.
- BYETTA can also be used with basal or long acting insulins in type 2 diabetes mellitus.

2. What you need to know before you use BYETTA

Do not use BYETTA:

- if you are hypersensitive (allergic) to exenatide or any of the other ingredients of BYETTA listed in section 6
- if you have decreased kidney function
- if you have gastrointestinal disease, such as delayed movement of food through the stomach due to muscle weakness (gastroparesis), dysmotility, and/or anatomical obstruction
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with BYETTA:

Talk to your doctor before using BYETTA:

- if you have severe problems with your stomach emptying (including gastroparesis) or food digestion. BYETTA slows stomach emptying so food passes more slowly through your stomach.
- if you have severe kidney disease or you are on dialysis.

Other considerations:

- When using BYETTA in combination with a sulphonylurea, as low blood sugar (hypoglycaemia) can occur. Ask your doctor or pharmacist if you are not sure if any of your other medicines contain a metformin or a sulphonylurea.

- If you lose weight rapidly at a rate of > 1,5 kg per week as weight loss of this rate may have harmful consequences.

- Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving BYETTA. Pancreatitis can be a serious, potentially life-threatening medical condition.

Tell your doctor if you have had pancreatitis, gall stones, alcoholism or very high triglycerides.

These medical conditions can increase your chance of getting pancreatitis, or getting it again, whether or not you are using BYETTA.

Call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Children and adolescents

Do not give BYETTA to children and adolescents less than 18 years as there is no insufficient experience with BYETTA in this age group.

Other medicines and BYETTA

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

- BYETTA slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

- Ask your doctor if the time at which you take any tablets (for example, birth control pills, antibiotics) should be changed. For tablets that you need to take with food, it may be best if they are taken at a meal or a snack when BYETTA is not administered.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

BYETTA with food, drink and alcohol

- Use BYETTA at any time within the 60 minutes (1 hour) before your meal (see “How to use BYETTA”). Do not use BYETTA after your meal.

Pregnancy, breastfeeding and fertility

- The use of BYETTA during pregnancy is contraindicated.
- You should not breastfeed your baby while using BYETTA.

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 health care provider for advice before using this medicine.

Driving and using machines

- A lower blood sugar (hypoglycaemia) can occur, especially if you use BYETTA in combination with a sulphonylurea or insulin. Hypoglycaemia may reduce your ability to concentrate. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery).

BYETTA contains metacresol and sodium

Metacresol may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

3. How to use BYETTA

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

Adults:

- Always use BYETTA exactly as your doctor or diabetes nurse has told you. You should check with your doctor, diabetes nurse or pharmacist if you are unsure.
- Two presentations of BYETTA are available: BYETTA 5 µg (microgram) and BYETTA 10 µg (microgram). Your doctor may tell you to use BYETTA 5 microgram to start with. After using BYETTA 5 microgram for 30 days the doctor may increase your dose to BYETTA 10 microgram. One injection of your pre-filled pen will give you your dose. Do not change your dose unless your doctor has told you to.
- BYETTA should be injected twice a day at any time within the 60 minutes (1 hour) before your morning and evening meals, or before your two main meals of the day, which should be about 6 hours or more apart. Do not use BYETTA after your meal.
- BYETTA is injected under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm.
- BYETTA should be injected under the skin and not into a vein or into the muscle.
- If you are using BYETTA and an insulin you must make two separate injections.
- See the accompanying Pen User Manual for instructions for using the BYETTA Pen.
- Your doctor or nurse must teach you how to inject BYETTA before you use it for the first time.
- Pen needles are not included. Ask your doctor or nurse, which needle size is best for you.
- Use a new injection needle for each injection and dispose of it after each use. This medicine is for you; never share a BYETTA pen with others.

If you take more BYETTA than you should

- If you use too much BYETTA you may need medical treatment right away. Too much BYETTA can cause nausea, vomiting, dizziness, or symptoms of low blood sugar.

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

If you forget to use BYETTA

- If you miss a dose of BYETTA, skip that dose and use your next dose at the next prescribed time. Do not use an extra dose or increase the amount of your next dose to make up for the one you missed. Do not use BYETTA after your meal.

If you stop using BYETTA

If you feel you should stop using BYETTA consult your doctor. If you stop BYETTA this can affect your blood sugar levels.

4. Possible side effects

BYETTA can have side effects.

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

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

- Severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis. Cases of inflammation of the pancreas (pancreatitis) have been reported in

patients receiving BYETTA. Pancreatitis can be a serious, potentially life-threatening medical condition.

Tell your doctor if you have had pancreatitis, gall stones, alcoholism or very high triglycerides. These medical conditions can increase your chance of getting pancreatitis, or getting it again, whether or not you are using BYETTA.

- Swollen face, tongue or throat
- Difficulty to swallow
- Hives and difficulties to breathe

These are all very serious side effects. If you have them, you may have had a serious reaction to BYETTA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea
- vomiting
- diarrhoea
- dizziness
- headache
- feeling jittery
- pain in the stomach area
- bloating
- indigestion
- increased sweating
- loss of energy and strength
- heartburn
- injection site reactions (redness)

- decreased weight
- reduced appetite
- hypoglycaemia

When BYETTA is used with a medicine that contains a sulphonylurea or insulin, low blood sugar (hypoglycaemia) can occur. The dose of your sulphonylurea medicine may need to be reduced while you use BYETTA. The signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, and feeling jittery. Your doctor should tell you how to treat low blood sugar.

Less frequent side effects:

- unusual taste in the mouth
- burping
- constipation
- gas (flatulence)
- angioedema (swelling of the face and throat)
- hypersensitivity (rashes, itching and rapid swelling of the tissues of the neck, face, mouth or throat)
- decrease in kidney function
- dehydration, sometimes with a decrease in kidney function
- drowsiness
- hair loss
- a delay in the emptying of the stomach

Frequency unknown:

- bleeding or bruising more easily than normal due to low level of blood platelets
- Changes in INR (measurement of blood thinning) have been reported when used together with warfarin.

If any of the side effects gets serious, or 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 SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BYETTA.

5. How to store BYETTA

- Store your BYETTA Pen, pen needles and all medicines out of reach of children.
- Do not use BYETTA after the expiry date, which is stated on the label.
- Use a BYETTA Pen for only 30 days. Dispose of a used BYETTA Pen after 30 days, even if some medicine remains in the pen.
- Do not use BYETTA if you notice particles in the solution or if it is cloudy or coloured.
- Prior to first use, store your BYETTA Pen in the original carton in a refrigerator at 2 °C to 8 ºC. Once in use, your BYETTA Pen should be stored at or below 25 ºC.
- Protect from light. Do not freeze. Discard any BYETTA Pen that has been frozen.
- Do not store the BYETTA Pen with the needle attached. If the needle is left on, medicine may leak from the BYETTA Pen or air bubbles may form in the cartridge.
- Ask your pharmacist how to dispose of medicines no longer required.
- 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 BYETTA contains

- The active substance is exenatide. Each millilitre (ml) of the solution for injection contains 0,25 milligrams (mg) of exenatide. Two prefilled pens are available to deliver unit doses of 5 µg (microgram) or 10 µg (microgram).
- The other ingredients are metacresol, mannitol, glacial acetic acid, sodium acetate trihydrate and water for injection.

What BYETTA looks like and contents of the pack

- BYETTA (solution for injection) is a clear and colourless liquid (solution for injection) filled in a glass cartridge. The cartridge is assembled into a disposable pen-injector (pen). Each pen contains sixty doses in a Type I clear colourless glass cartridge with a light grey rubber plunger, light grey rubber disc, and a gold finish aluminium seal.

- BYETTA 5 µg (microgram) and 10 µg (microgram) (solution for injection) are supplied in pack size of 1 pen.

Holder of Certificate of Registration

AstraZeneca Pharmaceuticals (Pty) Ltd

Building 2, Northdowns Office Park

17 Georgian Crescent West

Bryanston, Johannesburg, 2191

South Africa

This leaflet was last revised in

TBA

Registration numbers

BYETTA 5 µg: 41/34/0068

BYETTA 10 µg: 41/34/0069

Access to the corresponding Professional Information

TBA