Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL-METFORMIN

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AUSTELL–METFORMIN 500 mg TABLETS

AUSTELL–METFORMIN 850 mg TABLETS

Read all of this leaflet carefully before you start taking AUSTELL-METFORMIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUSTELL-METFORMIN** 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 AUSTELL- METFORMIN CONTAINS

Each film coated tablet contains 500 mg & 850 mg of the active ingredient metformin hydrochloride.

Other ingredients are

Tablet core:

coloidal anhydrous silica, magnesium stearate, povidone (PVPk - 30), sodium starch glycolate, starch maize

Tablet Coating:

hypromellose, macrogol 6000, propylene glycol, purified talc, titanium dioxide (E171).

WHAT AUSTELL- METFORMIN IS USED FOR

AUSTELL-METFORMIN is indicated in Non- insulin dependent diabetes when diet has failed and especially if the patient is overweight.

BEFORE YOU TAKE AUSTELL-METFORMIN

Do not take **AUSTELL-METFORMIN** tablets**:**

- If you are hypersensitive (allergic) to metformin hydrochloride or **any of the other ingredients of AUSTELL-METFORMIN (WHAT AUSTELL**- METFORMIN CONTAINS).
- If you suffer renal impairment.
- If you suffer from hepatic disease, a past history of lactic acidosis (of any cause), cardiac failure, or chronic lung disease, diabetic come, ketoacidosis.
- If you suffer from severe infection or trauma.
- If you are alcoholic.
- If you are on a low calorie diet.

Pregnancy & breastfeeding:

If you are pregnant or breast feeding your baby before taking this medicine please contact your doctor, pharmacist or other healthcare professional for advice.

During pregnancy, you need insulin to treat your diabetes. Tell your doctor so that he or she may change your treatment. This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machinery:

AUSTELL-METFORMIN on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines.

However, take special care if you take **AUSTELL-METFORMIN** together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

Taking other medicines with AUSTELL-METFORMIN:

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

AUSTELL- METFORMIN with Alcohol

Avoid excessive alcohol intake while taking **AUSTELL-METFORMIN** since this may increase the risk of lactic acidosis.

Other medicines and AUSTELL- METFORMIN

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, as this may lead to kidney failure and increase risk of lactic acidosis, you must stop taking **AUSTELL- METFORMIN** before or at the time of injection,. Your doctor will decide when you

must stop and when to restart your treatment with **AUSTELL-METFORMIN**.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of **AUSTELL- METFORMIN**:

- medicines which increase urine production (diuretics).

- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- beta-2 agonists such as salbutamol or terbutaline (used to treat asthma).
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).
- medicines that may change the amount of **AUSTELL-METFORMIN** in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib,
  isavuconazole, crizotinib, olaparib).
- other medicines used to treat diabetes.

HOW TO TAKE AUSTELL- METFORMIN

Do not share medicines prescribed for you with any other person. Always take **AUSTELL-METFORMIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

In Adults:

It is important that **AUSTELL-METFORMIN** tablets be taken in divided doses with meals.

An initial dose of **AUSTELL-METFORMIN** tablets is one 850 mg tablet twice a day or one 500 mg tablet three times a day with or without food is recommended.

You may achieve good diabetic control within a few days, but it is not unusual for the full effect to be delayed for up to two weeks.

If diabetic control is incomplete, your doctor may cautiously increase the dosage to a maximum of 3 g daily. Once control has been obtained it may be possible to reduce the dosage of **AUSTELL-METFORMIN**.

AUSTELL-METFORMIN should not be used in elderly with impaired renal function.

In children:

AUSTELL-METFORMIN tablets are not recommended for use in children

"In the event of over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control center"

POSSIBLE SIDE EFFECTS

AUSTELL-METFORMIN can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking **AUSTELL-METFORMIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Lactic acidosis: symptoms include vomiting, stomach ache (abdominal pain), muscle cramps, a general feeling of not being well with severe tiredness, difficulty breathing and reduced body temperature and heartbeat.
- Liver disease: which will be determined by tests conducted by your doctor or healthcare professional, symptoms include tiredness, loss of appetite, weight loss, yellowing of the skin and eyes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AUSTELL-METFORMIN**. 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:

- Loss of appetite, feeling sick (nausea), being sick (vomiting) abdominal pain and diarrhea.
- Changes in taste.
- Redness of the skin, itching skin or skin rash.
- Low vitamin B_{12} levels: which will be determined by tests conducted by your doctor or healthcare professional.

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

STORING AND DISPOSAL OF AUSTELL-METFORMIN

Keep this medicine in a dry place at or below 25 °C. Protect from light.

Do not transfer the medicine to any other container.

Do not share medicines prescribed for you with others.

DO NOT USE AFTER THE DATE, WHICH IS STAMPED ON THE PACK.

Keep the blisters in the carton until required for use.

Keep the container tightly closed.

"KEEP ALL MEDICINES OUT OF REACH OF CHILDREN."

Return all unused medicine to your pharmacist.

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

PRESENTATION OF AUSTELL-METFORMIN

AUSTELL-METFORMIN 500 mg:

Blister pack (clear PVDC coated PVC film and aluminium foil) of 56's, 84's and 100's.

Bulk pack (HDPE container) of 500's tablets.

AUSTELL-METFORMIN 850 mg:

Blister pack (clear PVDC coated PVC film and aluminium foil) of 28's, 56's, 60's and 84's.

Bulk pack (HDPE container) of 300's tablets.

IDENTIFICATION OF AUSTELL-METFORMIN

AUSTELL-METFORMIN 500 mg:

White coloured, film coated, round, biconvex tablets with ‘500’ embossing.

AUSTELL-METFORMIN 850 mg:

White coloured, film coated, round, biconvex tablets with ‘850’ embossing

REGISTRATION NUMBER/REFERENCE NUMBER

AUSTELL-METFORMIN 500 mg: A38/21.2/0504

AUSTELL-METFORMIN 850 mg: A38/21.2/0505

NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 23 September 2005

Date of the most recent amendment to the patient information leaflet as approved by the Authority: