DRAFT COPY

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DRAFT ISSUE: 2

REASON FOR CHANGE: CUTTER GUIDE UPDATE

SUPPLIER ISSUE DATE: 20.5.2025

DIMENSIONS 86 x 40 mm

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Client: ALMUS UK
Project: MOS0531 HYDRALAZINE 25MG TABLETS LBL-PIL
Item(s): Label/Leaflet
Category: Almus UK
Date: 20.5.2025

Colours used:

🟩	🟨	🟥	■
PMS 349	PMS 142	PMS 1788	BLACK

🟪	■
CUTTER	BRAILLE

This scale measures 100mm when artwork is 100%
0 10 20 30 40 50 60 70 80 90 100

Proportions used:

Calculation:	Label
FOP text:	10.2pt
Image size (% of import):	N/A
BOP Font size (pt):	10 pt
BOP Leading size (pt):	9.8 pt
EAN %:	100% imported size from previous artwork

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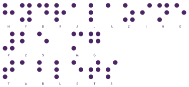
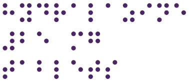
Modifications:

Draft 1: Cutterguide update. Reflow text to ne dimensions. Increase text point size to use space. Inside front page of label branded area text increased 150% to use space. **Draft 2:** Text area layout adjustment, reduce leading to fit text within “tolerance”. Add braille to another panel. .





Leaflet outside (Prima)
86 mm
Page 1 Glue

Leaflet inside (Sekunda)
86 mm
Page 2

Hydralazine Tablets
Film-Coated

25 mg
ALMUS

56 Film-Coated Tablets Oral use

Each film-coated tablet contains: 25 mg hydralazine hydrochloride. **Dosage:** Oral use. Read the package leaflet before use. **Keep out of the sight and reach of children.** Do not store above 25°C. Store in the original package in order to protect from light.
MA Holder: Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K. PL 04569/0050 **POM**
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Leaflet outside (Prima)
86 mm
Page 3

Mylan

Package leaflet: Information for the patient

HYDRALAZINE 25 mg FILM-COATED TABLETS
HYDRALAZINE 50 mg FILM-COATED TABLETS
(hydralazine hydrochloride)

Leaflet inside (Sekunda)
86 mm
Page 4

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

Leaflet outside (Prima)
86 mm
Page 5

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

1. What Hydralazine is and what it is used for
2. What you need to know before you take Hydralazine

Leaflet inside (Sekunda)
86 mm
Page 6

3. How to take Hydralazine
4. Possible side effects
5. How to store Hydralazine
6. Contents of the pack and other information

1. What Hydralazine is and what it is used for

Hydralazine belongs to a group of medicines called antihypertensives.
Hydralazine can be used along with other medicines:

Leaflet inside (Sekunda)
86 mm
Page 7

- to reduce high blood pressure (hypertension)
- to treat moderate and serious heart failure.

Anti-hypertensives work by lowering blood pressure. High blood pressure increases the workload of the heart and arteries (blood vessels) and if left untreated, can lead to damage of the blood vessels of the brain, heart and kidneys.

2. What you need to know before you take Hydralazine

Do not take Hydralazine:

- if you are allergic to hydralazine hydrochloride or dihydralazine, or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from the condition systemic lupus erythematosus (SLE) or a related disease
- if you suffer from an unusually fast heartbeat

- if you have heart failure, heart valve problems (aortic or mitral stenosis) or inflammation of the heart (constrictive pericarditis)
- if you have an aortic aneurysm (swelling in the wall of the aorta which can cause sweating, a fast heartbeat, and abdominal or back pain)
- if you have an enlarged heart often caused by lung disease (cor pulmonale)
- if there is a family history of the rare condition porphyria.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydralazine:

- if you have liver or kidney problems.
- if you suffer from hardened arteries (coronary artery disease), chest pain (angina) or are at risk of having a stroke.
- if you are recovering from a heart attack.

- if you need surgery.

Other medicines and Hydralazine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or any of the following:

- other antihypertensives including medicines used to widen the blood vessels such as diazoxide or nitrates, beta-blockers (e.g. propranolol), ACE inhibitors (e.g. captopril), “water” tablets (diuretics e.g. furosemide) and medicines known as “calcium channel blockers” (e.g. verapamil)

- medicines used to treat depression e.g. tricyclic antidepressants such as dosulepin, monoamine oxidase inhibitors (MAOIs) such as phenelzine or to treat a mental illness (e.g. Chlorpromazine)

- medicines used to treat anxiety such as tranquillisers (e.g. diazepam)
- anti-inflammatory painkillers (NSAIDs) e.g. indometacin
- corticosteroids e.g. prednisolone
- medicines which slow down the nervous system (CNS depressants)
- carbenoxolone, used to treat stomach ulcers

- anaesthetics
- medicines containing oestrogens e.g. HRT, or the combined oral contraceptive pill.

Ask your doctor or pharmacist for advice before taking any medicine.

Hydralazine with food and drink and alcohol

Taking Hydralazine with food may decrease the amount of the medicine in your system, therefore, take it before food.

Alcohol may increase the effects of hydralazine causing side effects such as dizziness.

Pregnancy and breast-feeding

Hydralazine should only be used in the last few months of pregnancy If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or use machines if you suffer from headaches, dizziness or have difficulty concentrating while taking this medicine. Speak to your doctor or pharmacist for advice.

Hydralazine contains sodium Hydralazine 25 mg and 50 mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say they are essentially ‘sodium-free’.

Hydralazine contains lactose The 50 mg strength tablets contain **lactose.** If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

Hydralazine contains Sunset yellow (E110)

The 50 mg tablets also contain the colouring **Sunset yellow (E110)** which may cause allergic reactions in some people.

3. How to take Hydralazine

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

If you are taking Hydralazine for a long time, your doctor may wish to test your urine and blood every six months.

Your doctor will start you on a low dose of Hydralazine and gradually increase the dose depending on your condition.

The recommended dose is:

Adults

Hypertension

The recommended starting dose is 25 mg of Hydralazine twice a day, increasing to a maximum total dose of 200 mg of Hydralazine a day.

Heart failure

Treatment is started in hospital with a dose of 25 mg of Hydralazine three or four times a day; if necessary, increasing to 50-75 mg of Hydralazine four times a day.

A small group of patients can break down hydralazine in their body at a different rate to the majority of patients. This can lead to unwanted effects. Your doctor will check for this possibility, and if this occurs, will change your dose of Hydralazine as needed. You should carry on taking your medicine as long as your doctor or pharmacist tells you to, even if you feel better.

Use in children and adolescents

Hydralazine **should not** be given to children or adolescents.

Method of administration

Swallow the tablets with a glass of water.

If you take more Hydralazine than you should

The signs and symptoms of hydralazine overdose include low blood pressure, a racing heart beat, headache and generalised skin flushing. If you take more Hydralazine than you should contact your doctor or hospital emergency department immediately.

If you forget to take Hydralazine
If you forget to take a dose of Hydralazine, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Hydralazine
Do not stop taking Hydralazine without talking to your doctor, even if you feel better, because it may make your illness worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Hydralazine can cause side effects, although not everybody gets them.
If any of the following happen, stop taking this medicine and see your doctor straight away or go to the nearest hospital immediately.

Common
(may affect up to 1 in 10 people)
- systemic lupus erythematosus (SLE) or a related disease with signs such as joint pain (similar to rheumatoid arthritis), fever, change in blood count and skin rash

Rare
(may affect up to 1 in 1,000 people)
- swelling of the hands and lower legs,

breathlessness, tightness of the chest, sharp chest pain, which is worse when breathing in, feeling dizzy
- allergic reactions such as itchy red and swollen skin, red skin rash on cheeks and other parts of the body, skin rashes which may be severe
- signs of reduced numbers of different blood cells, which may cause unusual bruising or bleeding of the skin (reduced number of

platelets), frequent infections, fever, chills, sore throat or mouth ulcers (reduced number of white blood cells)
- liver problems, which can cause yellowing of the skin or whites of the eyes, dark urine and pale stools
- blood in the urine (the urine may look red or pink)

Very rare
(may affect up to 1 in 10,000 people)
- illness resulting from the destruction of red blood cells with signs such as looking pale, feeling tired, breathlessness, yellowing of the skin and/or eyes
- a reduction in all types of blood cells, which may cause frequent infections, unusual bruising or bleeding of the skin or you to feel tired

and breathless
- changes in how much you urinate, difficulty or pain when passing urine, lower back pain, fever, nausea and vomiting – these may be signs of kidney problems
- severe pain in the stomach with bloating, cramps constipation and vomiting
- protruding eyes

Other possible side effects
Very common
(may affect more than 1 in 10 people)
- fast or irregular heartbeat
- headache

Common
(may affect up to 1 in 10 people)
- low blood pressure
- muscle or joint pain

- swelling of the joints
- feeling or being sick
- diarrhoea, upset stomach
- chest pain
- flushing
- dizziness
- blocked nose

Rare
(may affect up to 1 in 1,000 people)

- protein in the urine which would be seen in a urine test
- increased levels of creatinine in the blood which would be seen in a blood test
- loss of appetite, weight loss
- feeling generally unwell
- feeling anxious or agitated
- itchy, red, infected eyes (conjunctivitis), watery or swollen eyes.

- abdominal swelling caused by enlarged liver or fluid retention in the body
- swelling of blood vessels.
  Signs include fever, general aches and pain, loss of appetite, weight loss and tiredness
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- increase in some white blood cells which may be seen in a blood test

- decrease in some red blood cells which may be seen in a blood test

Very rare
(may affect up to 1 in 10,000 people)
- an increase in blood pressure
- inflammation of the nerves, which may cause tingling or numbness especially in the hands, arms, feet or legs
- painful swelling in the arms or legs

- swollen (lymph) glands in the armpits, neck or groins
- feeling depressed
- seeing, feeling or hearing things that are not there (hallucinations)
- abnormal swelling of the spleen (splenomegaly). You may notice signs such as being unable to eat a large meal, feeling discomfort, fullness, or pain on the upper left

side of the abdomen; this pain may spread to your left shoulder

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.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydralazine

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

Do not use this medicine after the expiry date which is stated on the label or container after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.
Do not throw away any medicines via wastewater or household waste.

Leaflet inside (Sekunda)
86 mm
Page 40

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 Hydralazine contains

The active substance is hydralazine hydrochloride.

Each 25 mg tablet contains 25 mg of

Leaflet outside (Prima)
86 mm
Page 41

hydralazine hydrochloride.
Each 50 mg tablet contains 50 mg of hydralazine hydrochloride.
The other ingredients are microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, sodium starch glycolate (in 50 mg strength only), disodium edetate, talc and magnesium stearate.
The coating for the 25 mg strength tablets

15 mm
Tab

5
mm

Leaflet outside (Prima)
86 mm
Front page outside

PEEL HERE BUT DO NOT REMOVE

Hydralazine Tablets
Film-Coated

25 mg
ALMUS

56 Film-Coated Tablets Oral use

Each film-coated tablet contains: 25 mg hydralazine hydrochloride.
Dosage: Oral use. Read the package leaflet before use.
Keep out of the sight and reach of children.
Do not store above 25°C. Store in the original package in order to protect from light.
PL 04569/0050 POM UK Only MA Holder: Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K.

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Variable Data Information box for online printing - United Kingdom

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* Will be printed only after serialisation go live
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Version: 1422541

Leaflet inside (Sekunda)
86 mm
Page 42

contains diethyl phthalate, hydroxypropylcellulose, ethylcellulose, carnauba wax, red iron oxide (E172),’ hypromellose, titanium dioxide (E171) and Quinoline yellow (E104).
The coating for the 50 mg strength tablets contains titanium dioxide (E171), lactose (see section 2 “Hydralazine contains lactose”), hypromellose, macrogol, indigo carmine (E132),

Leaflet inside (Sekunda)
86 mm
Page 43

sunset yellow (E110) (see section 2 “Hydralazine contains sunset yellow (E110)”) iron oxide yellow (E172) and erythrosine (E127).

What Hydralazine looks like and contents of the pack
25 mg tablets are yellow film coated tablet marked “HE 25” on one side and “G” on the reverse.
50 mg tablets are pink film coated tablets

Total of label / Braille placement only – CCL work area

15 mm
Tab

5
mm

86 mm

24 mm

For proofreading of Braille

15 mm
Tab

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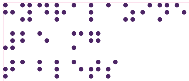
86 mm

24 mm



Leaflet outside (Prima)
86 mm
Page 44

marked “HE 50” on one side and “G” on the reverse.
Hydralazine Tablets 25 mg and 50 mg are available in glass or plastic containers and blisters of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250 and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K.

Leaflet inside (Sekunda)
86 mm
Page 45

Manufacturers Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, U.K. Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., Mylan utca 1., Komárom, 2900, Hungary.

This leaflet was last revised in 09/2024

Base label (Selfadhesive)

20 mm
Tab/Glue

86 mm
Glue

24 mm

Leaflet outside (Prima)
86 mm
Page 46

Leaflet inside (Sekunda)
86 mm
Page 47 (Front page inside)

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15 mm
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