The plasma protein binding of vildagliptin is low (9.3%) and vildagliptin distributes equally between plasma and red blood cells. The mean volume of distribution of vildagliptin at steady-state after intravenous administration (V_{ss}) is 71 litres, suggesting extravascular distribution.

Biotransformation

Metabolism is the major elimination pathway for vildagliptin in humans, accounting for 69% of the dose. The major metabolite (LAY 151) is pharmacologically inactive and is the hydrolysis product of the cyano moiety, accounting for 57% of the dose, followed by the amide hydrolysis product (4% of dose). In vitro data in human kidney microsomes suggest that the kidney may be one of the major organs contributing to the hydrolysis of vildagliptin to its major inactive metabolite, LAY151. DPP-4 contributes partially to the hydrolysis of vildagliptin based on an *in vivo* study using DPP-4 deficient rats. Vildagliptin is not metabolised by CYP 450 enzymes to any quantifiable extent. Accordingly, the metabolic clearance of vildagliptin is not anticipated to be affected by co-medications that are CYP 450 inhibitors and/or inducers. *In vitro* studies demonstrated that vildagliptin does not inhibit/induce CYP 450 enzymes. Therefore, vildagliptin is not likely to affect metabolic clearance of co-medications metabolised by CYP 1A2, CYP 2C8, CYP 2C9, CYP 2C19, CYP 2D6, CYP 2E1 or CYP 3A4/5.

Elimination

Following oral administration of [^{14}C] vildagliptin, approximately 85% of the dose was excreted into the urine and 15% of the dose is recovered in the faeces. Renal excretion of the unchanged vildagliptin accounted for 23% of the dose after oral administration. After intravenous administration to healthy subjects, the total plasma and renal clearances of vildagliptin are 41 and 13 l/h, respectively. The mean elimination half-life after intravenous administration is approximately 2 hours. The elimination half-life after oral administration is approximately 3 hours.

Linearity / non-linearity

The C_{max} for vildagliptin and the area under the plasma concentrations versus time curves (AUC) increased in an approximately dose proportional manner over the therapeutic dose range.

Characteristics in patients

Gender

No clinically relevant differences in the pharmacokinetics of vildagliptin were observed between male and female healthy subjects within a wide range of age and body mass index (BMI). DPP-4 inhibition by vildagliptin is not affected by gender.

Age

In healthy elderly subjects (≥ 70 years), the overall exposure of vildagliptin (100 mg once daily) was increased by 32%, with an 18% increase in peak plasma concentration as compared to young healthy subjects (18-40 years). These changes are, however, not considered to be clinically relevant. DPP-4 inhibition by vildagliptin is not affected by age.

Hepatic impairment

The effect of impaired hepatic function on the pharmacokinetics of vildagliptin was studied in patients with mild, moderate and severe hepatic impairment based on the Child-Pugh scores (ranging from 6 for mild to 12 for severe) in comparison with healthy subjects. The exposure to vildagliptin after a single dose in patients with mild and moderate hepatic impairment was decreased (20% and 8%, respectively), while the exposure to vildagliptin for patients with severe impairment was increased by 22%. The maximum change (increase or decrease) in the exposure to vildagliptin is ~30%, which is not considered to be clinically relevant. There was no correlation between the severity of the hepatic disease and changes in the exposure to vildagliptin.

Renal impairment

In subjects with mild, moderate, or severe renal impairment, systemic exposure to vildagliptin was increased (C_{max} 8-66%; AUC 32-134%) and total body clearance was reduced compared to subjects with normal renal function.

Ethnic group

Limited data suggest that race does not have any major influence on vildagliptin pharmacokinetics.

5.3 Preclinical safety data

Intra-cardiac impulse conduction delays were observed in dogs with a no-effect dose of 15 mg/kg (7-fold human exposure based on C_{max}).

Accumulation of foamy alveolar macrophages in the lung was observed in rats and mice. The no-effect dose in rats was 25 mg/kg (5-fold human exposure based on AUC) and in mice 750 mg/kg (142-fold human exposure).

Gastrointestinal symptoms, particularly soft faeces, mucoid faeces, diarrhoea and, at higher doses, faecal blood were observed in dogs. A no-effect level was not established.

Vildagliptin was not mutagenic in conventional *in vitro* and *in vivo* tests for genotoxicity.

A fertility and early embryonic development study in rats revealed no evidence of impaired fertility, reproductive performance or early embryonic development due to vildagliptin. Embryo-foetal toxicity was evaluated in rats and rabbits. An increased incidence of wavy ribs was observed in rats in association with reduced maternal body weight parameters, with a no-effect dose of 75 mg/kg (10-fold human exposure). In rabbits, decreased foetal weight and skeletal variations indicative of developmental delays were noted only in the presence of severe maternal toxicity, with a no-effect dose of 50 mg/kg (9-fold human exposure). A pre- and postnatal development study was performed in rats. Findings were only observed in association with maternal toxicity at $\geq$ 150 mg/kg and included a transient decrease in body weight and reduced motor activity in the F1 generation.

A two-year carcinogenicity study was conducted in rats at oral doses up to 900 mg/kg (approximately 200 times human exposure at the maximum recommended dose). No increases in tumour incidence attributable to vildagliptin were observed. Another two-year carcinogenicity study was conducted in mice at oral doses up to 1,000 mg/kg. An increased incidence of mammary adenocarcinomas and haemangiosarcomas was observed with a no-effect dose of 500 mg/kg (59-fold human exposure) and 100 mg/kg (16-fold human exposure), respectively. The increased incidence of these tumours in mice is considered not to represent a significant risk to humans based on the lack of genotoxicity of vildagliptin and its principal metabolite, the occurrence of tumours only in one species and the high systemic exposure ratios at which tumours were observed.

In a 13-week toxicology study in cynomolgus monkeys, skin lesions have been recorded at doses $\geq$ 5 mg/kg/day. These were consistently located on the extremities (hands, feet, ears and tail). At 5 mg/kg/day (approximately equivalent to human AUC exposure at the 100 mg dose), only blisters were observed. They were reversible despite continued treatment and were not associated with histopathological abnormalities. Flaking skin, peeling skin, scabs and tail sores with correlating histopathological changes were noted at doses $\geq$ 20 mg/kg/day (approximately 3 times human AUC exposure at the 100 mg dose). Necrotic lesions of the tail were observed at $\geq$ 80 mg/kg/day. Skin lesions were not reversible in the monkeys treated at 160 mg/kg/day during a 4-week recovery period.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, anhydrous
Cellulose, microcrystalline
Sodium starch glycolate (type A)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminium/Aluminium (PA/Al/PVC//Al) blister
Available in packs containing 7, 14, 28, 30, 90, 112 or 336 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Wimblehurst Road
Horsham
West Sussex, RH12 5AB
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Novartis Pharma GmbH
Roonstrasse 25
D-90429 Nürnberg
Germany

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable

- **OTHER CONDITIONS**

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance, as described in version 2.0 (23 February 2007) presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before and whilst the product is on the market.

Risk Management Plan
The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 2 (4 July 2007) of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted
- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the EMEA

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Galvus 50 mg tablets
vildagliptin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50 mg vildagliptin.

3. LIST OF EXCIPIENTS

Contains lactose (see leaflet for further information).

4. PHARMACEUTICAL FORM AND CONTENTS

7 tablets
14 tablets
28 tablets
30 tablets
56 tablets
60 tablets
90 tablets
112 tablets
180 tablets
336 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Wimblehurst Road
Horsham
West Sussex, RH12 5AB
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000	7 tablets
EU/0/00/000/000	14 tablets
EU/0/00/000/000	28 tablets
EU/0/00/000/000	30 tablets
EU/0/00/000/000	56 tablets
EU/0/00/000/000	60 tablets
EU/0/00/000/000	90 tablets
EU/0/00/000/000	112 tablets
EU/0/00/000/000	180 tablets
EU/0/00/000/000	336 tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Galvus 50 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Galvus 50 mg tablets
vildagliptin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Galvus 100 mg tablets
vildagliptin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 100 mg vildagliptin.

3. LIST OF EXCIPIENTS

Contains lactose (see leaflet for further information).

4. PHARMACEUTICAL FORM AND CONTENTS

7 tablets
14 tablets
28 tablets
30 tablets
90 tablets
112 tablets
336 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited
Wimblehurst Road
Horsham
West Sussex, RH12 5AB
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000	7 tablets
EU/0/00/000/000	14 tablets
EU/0/00/000/000	28 tablets
EU/0/00/000/000	30 tablets
EU/0/00/000/000	90 tablets
EU/0/00/000/000	112 tablets
EU/0/00/000/000	336 tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Galvus 100 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Galvus 100 mg tablets
vildagliptin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Novartis Europharm Limited

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Galvus 50 mg tablets
Galvus 100 mg tablets

Vildagliptin

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, diabetes nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Galvus is and what it is used for
2. Before you take Galvus
3. How to take Galvus
4. Possible side effects
5. How to store Galvus
6. Further information

1. WHAT GALVUS IS AND WHAT IT IS USED FOR

Galvus belongs to a group of medicines called "oral antidiabetics".

Galvus is used to treat patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

Galvus works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level.

Your doctor will prescribe Galvus together with certain other antidiabetic medicines which you will already be taking to control diabetes, if one medicine alone is not enough to control your blood sugar level.

Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. BEFORE YOU TAKE GALVUS

Do not take Galvus:
- if you are allergic (hypersensitive) to vildagliptin or any of the other ingredients of Galvus (see section 6: Further information). If you think you may be allergic to vildagliptin or any of the other ingredients of Galvus, do not take this medicine and talk to your doctor.

Take special care with Galvus:
If any of these apply to you, tell your doctor before taking Galvus.
- if you have type 1 diabetes (i.e. your body does not produce insulin).
- if you have moderate or severe kidney disease.
- if you are on dialysis.
- if you have severe liver disease.
- if you suffer from heart failure.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Galvus. Should these occur, you should promptly consult your doctor.

The use of Galvus in children and adolescents is not recommended.

Taking other medicines

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

Your doctor may wish to alter your dose of Galvus if you are taking other medicines (such as medicines so called thiazides, corticosteroids, thyroid products and certain products affecting the nervous system).

Taking Galvus with food and drink
You can take Galvus with or without food.

Pregnancy and breast-feeding
Women who are pregnant or plan to become pregnant should consult their doctor before taking Galvus. You should not use Galvus during pregnancy.
It is not known if Galvus passes into breast milk. You should not use Galvus if you are breast-feeding or plan to breast-feed.

Driving and using machines
If you feel dizzy while taking Galvus, do not drive or use machines.

Important information about some of the ingredients of Galvus
Galvus contains lactose (milk sugar). 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 GALVUS

Always take Galvus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take
The amount of Galvus people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Galvus to take.

The usual dose of Galvus is either:
- 50 mg daily taken as one dose in the morning if you are taking Galvus with another medicine called a sulphonylurea, or
- 100 mg daily taken as one dose in the morning or as 50 mg in the morning and 50 mg in the evening if you are taking Galvus with another medicine called metformin or a glitazone.

Your doctor will prescribe Galvus together with another medicine to control your blood sugar level.

When and how to take Galvus
- Take this medicine in the morning or in the morning and evening.
- Swallow the tablets whole with some water.

How long to take Galvus
- Take Galvus every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.
- Do not stop taking Galvus unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

If you take more Galvus than you should
If you take too many Galvus tablets, or if someone else has taken your medicine, **talk to your doctor straight away.** Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Galvus
If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Galvus can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:
You should see your doctor immediately if you experience the following symptoms which may indicate a reaction called "angioedema":
- Swollen face, tongue or throat
- Difficulty swallowing
- Difficulties breathing
- Sudden onset rash or hives

Other side effects
Common side effects (likely to occur in fewer than 1 in 10 patients)
Uncommon side effects (likely to occur in fewer than 1 in 100 patients)
Very rare side effects (likely to occur in fewer than 1 in 10,000 patients)

Some patients have had the following side effects while taking Galvus and metformin:
- Common: Trembling, headache, dizziness, nausea
- Uncommon: Tiredness

Some patients have had the following side effects while taking Galvus and a sulphonylurea:
- Common: Trembling, headache, dizziness, weakness
- Uncommon: Constipation
- Very rare: Sore throat, runny nose

Some patients have had the following side effects while taking Galvus and a glitazone:
- Common: Weight increase, swollen hands, ankle or feet (oedema)
- Uncommon: Headache, weakness

Some patients have had the following side effects while taking Galvus alone :

- Common: Dizziness
- Uncommon: Headache, constipation, swollen hands, ankle or feet (oedema), joint pain
- Very rare: Sore throat, runny nose, fever

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GALVUS

- Keep out of the reach and sight of children.
- Do not use Galvus after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- Do not use any Galvus pack that is damaged or shows signs of tampering.

6. FURTHER INFORMATION

What Galvus contains
- The active substance is vildagliptin.
  Galvus 50 mg tablets: Each tablet contains 50 mg vildagliptin.
  Galvus 100 mg tablets: Each tablet contains 100 mg vildagliptin.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, sodium starch glycolate (type A) and magnesium stearate.

What Galvus looks like and contents of the pack
Galvus 50 mg tablets are round, white to light yellowish and flat, with "NVR" on one side and "FB" on the other.
Galvus 100 mg tablets are elongated and white to light yellowish, with "NVR" on one side and "HL" on the other.

Galvus 50 mg tablets are available in packs containing 7, 14, 28, 30, 56, 60, 90, 112, 180 or 336 tablets.
Galvus 100 mg tablets are available in packs containing 7, 14, 28, 30, 90, 112 or 336 tablets.
Not all pack sizes may be marketed in your country.

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Manufacturer
Novartis Pharma GmbH
Roonstraße 25
D-90429 Nuremberg
Germany

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This leaflet was last approved in