Metabolism
Febuxostat is extensively metabolized by conjugation *via* uridine diphosphate glucuronosyltransferase (UDPGT) enzyme system and oxidation *via* the cytochrome P450 (CYP) system. Four pharmacologically active hydroxyl metabolites have been identified, of which three occur in plasma of humans. *In vitro* studies with human liver microsomes showed that those oxidative metabolites were formed primarily by CYP1A1, CYP1A2, CYP2C8 or CYP2C9 and febuxostat glucuronide was formed mainly by UGT 1A1, 1A8, and 1A9

Elimination
Febuxostat is eliminated by both hepatic and renal pathways. Following an 80 mg oral dose of ^{14}C-labeled febuxostat, approximately 49% of the dose was recovered in the urine as unchanged febuxostat (3%), the acyl glucuronide of the active substance (30%), its known oxidative metabolites and their conjugates (13%), and other unknown metabolites (3%). In addition to the urinary excretion, approximately 45% of the dose was recovered in the faeces as the unchanged febuxostat (12%), the acyl glucuronide of the active substance (1%), its known oxidative metabolites and their conjugates (25%), and other unknown metabolites (7%).

Special populations
Renal insufficiency
Following multiple doses of 80 mg of ADENURIC in patients with mild, moderate or severe renal insufficiency, the C_{max} of febuxostat did not change, relative to subjects with normal renal function. The mean total AUC of febuxostat increased by approximately 1.8-fold from 7.5 μg·h/ml in the normal renal function group to 13.2 μg.h/ml in the severe renal dysfunction group. The C_{max} and AUC of active metabolites increased up to 2- and 4-fold, respectively. However, no dose adjustment is necessary in patients with mild or moderate renal impairment.

Hepatic impairment
Following multiple doses of 80 mg of ADENURIC in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment, the C_{max} and AUC of febuxostat and its metabolites did not change significantly compared to subjects with normal hepatic function. No studies have been conducted in patients with severe hepatic impairment (Child-Pugh Class C).

Age
There were no significant changes observed in AUC of febuxostat or its metabolites following multiple oral doses of ADENURIC in elderly as compared to younger healthy subjects.

Gender
Following multiple oral doses of ADENURIC, the C_{max} and AUC were 24% and 12% higher in females than in males, respectively. However, weight-corrected C_{max} and AUC were similar between the genders. No dose adjustment is needed based on gender.

5.3 Preclinical safety data

Effects in non-clinical studies were generally observed at exposures in excess of the maximum human exposure.

Carcinogenesis, mutagenesis, impairment of fertility

In male rats, a statistically significant increase in urinary bladder tumours (transitional cell papilloma and carcinoma) was found only in association with xanthine calculi in the high dose group, at approximately 11 times human exposure. There was no significant increase in any other tumour type in either male or female mice or rats. These findings are considered a consequence of species specific purine metabolism and urine composition and of no relevance to clinical use.

A standard battery of test for genotoxicity did not reveal any biologically relevant genotoxic effects for febuxostat.

Febuxostat at oral doses up to 48 mg/kg/day was found to have no effect on fertility and reproductive performance of male and female rats.

There was no evidence of impaired fertility, teratogenic effects, or harm to the foetus due to febuxostat. There was high dose maternal toxicity accompanied by a reduction in weaning index and reduced development of offspring in rats at approximately 4.3 times human exposure. Teratology studies, performed in pregnant rats at approximately 4.3 times and pregnant rabbits at approximately 13 times human exposure did not reveal any teratogenic effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate
Hydroxypropylcellulose
Croscarmellose sodium
Silica, colloidal hydrated

Tablet coating
Opadry II, Yellow, 85F42129 containing:
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogols 3350
Talc
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

Clear (Aclar/PVC/Aluminium) blister of 14 tablets.

ADENURIC 120 mg is available in pack sizes of 28 and 84 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

Detailed information on this product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/

ANNEX II

A. 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(s) responsible for batch release

Patheon France
40 Boulevard de Champaret
FR-38300 Bourgoin Kallieu
France

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 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 2.0 (19 February 2008) 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
OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 80 mg film-coated tablets
Febuxostat

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 80 mg febuxostat.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.
See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

28 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For 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

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

Marketing Authorisation Holder:
Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

ADENURIC 80 mg

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 80 mg film-coated tablets
Febuxostat

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 80 mg febuxostat.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.
See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

84 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For 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

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

Marketing Authorisation Holder:
Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

ADENURIC 80 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 80 mg tablets
Febuxostat

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ipsen

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Mon
Tue
Wed
Thurs
Fri
Sat
Sun

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 120 mg film-coated tablets
Febuxostat

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 120 mg febuxostat.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.
See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

28 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For 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

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

Marketing Authorisation Holder:
Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

ADENURIC 120 mg

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 120 mg film-coated tablets
Febuxostat

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 120 mg febuxostat.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.
See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

84 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For 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

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

Marketing Authorisation Holder:
Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

ADENURIC 120 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

ADENURIC 120 mg tablets
Febuxostat

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ipsen

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Mon
Tue
Wed
Thurs
Fri
Sat
Sun

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

ADENURIC 80 mg film-coated tablets
Febuxostat

ADENURIC 120 mg film-coated tablets
Febuxostat

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

In this leaflet:

1. WHAT ADENURIC IS AND WHAT IT IS USED FOR

ADENURIC tablets are used to treat gout, which is associated with an excess of a chemical called uric acid (urate) in the body. In some people, the amount of uric acid builds up in the blood and may become too high to remain soluble. When this happens, urate crystals may form in and around the joints and kidneys. These crystals can cause sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). Left untreated, larger deposits called tophi (TOE-FI) may form in and around joints. These tophi may cause joint and bone damage.

ADENURIC works by reducing uric acid levels. Keeping uric acid levels low by taking ADENURIC once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long enough period can also shrink tophi.

2. BEFORE YOU TAKE ADENURIC

Do not take ADENURIC if you are:
- If you are allergic (hypersensitive) to febuxostat, the active ingredient of ADENURIC, or any of the other ingredients in these tablets.

Take special care with ADENURIC
Tell your doctor before you start to take this medicine:
- If you have or have had heart failure or heart problems
- If you are being treated for high uric acid levels as a result of cancer disease or Lesch-Nyhan syndrome (a rare inherited condition in which there is too much uric acid in the blood)
- If you have thyroid problems

If you are having a gout attack at the moment (a sudden onset of severe pain, tenderness, redness, warmth and swelling in a joint), wait for the gout attack to subside before first starting treatment with ADENURIC.

For some people, gout attacks may flare up when starting certain medicines that control uric acid levels. Not everyone gets flares, but you could get a flare-up even if you are taking ADENURIC, and

especially during the first weeks or months of treatment. It is important to keep taking ADENURIC even if you have a flare, as ADENURIC is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking ADENURIC every day.

Your doctor will often prescribe other medicines, if they are needed, to help prevent or treat the symptoms of flares (such as pain and swelling in a joint).

Your doctor may ask you to have blood tests to check that your liver is working normally.

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.

It is especially important to tell your doctor or pharmacist if you are taking medicines containing any of the following substances as they may interact with ADENURIC and your doctor may wish to consider necessary measures:

- Mercaptopurine (used to treat cancer)
- Azathioprine (used to reduce immune response)
- Theophylline (used to treat asthma)
- Warfarin (used to thin your blood if you have a heart condition)

Taking ADENURIC with food and drink
The tablets should be taken by mouth and can be taken with or without food.

Pregnancy and breast-feeding
It is not known if ADENURIC may harm your unborn child. Tell your doctor if you think you are pregnant or if you are planning to become pregnant as ADENURIC should not be used during pregnancy. It is not known if ADENURIC may pass into human breast milk. You should not use ADENURIC if you are breast feeding, or if you are planning to breastfeed.

Driving and using machines
No studies on the effects of ADENURIC on the ability to drive and use machines have been performed. However, you should be aware that you may experience dizziness, sleepiness and numbness or tingling sensation during treatment and should not drive or operate machines if affected.

Important information about some of the ingredients of ADENURIC
ADENURIC tablets contain lactose (a type of sugar). If you have been told that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. HOW TO TAKE ADENURIC

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

ADENURIC is available as either an 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.

- The usual dose is one tablet daily. The back of the blister pack is marked with the days of the week to help you check that you have taken a dose each day.
- The tablets should be taken by mouth and can be taken with or without food.

It is important that you do not stop taking ADENURIC unless your doctor tells you to.

Continue to take ADENURIC every day even when you are not experiencing gout flare or attack.

If you take more ADENURIC than you should

In the event of an accidental overdose ask your doctor what to do, or contact your nearest accident and emergency department.

If you forget to take ADENURIC
If you miss a dose of ADENURIC take it as soon as you remember unless it is almost time for your next dose, in which case miss out the forgotten dose and take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking ADENURIC
Do not stop taking ADENURIC without the advice of your doctor even if you feel better. If you stop taking ADENURIC your uric acid levels may begin to rise and your symptoms may worsen due to the formation of new crystals of urate in and around your joints and kidneys.

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

4. POSSIBLE SIDE EFFECTS

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

Common side effects (more than 1 in 100 patients but less than 1 in 10 patients) are:
- abnormal liver test results
- diarrhoea
- headache
- rashes
- feeling sick

Uncommon side effects (more than 1 in 1,000 patients but less than 1 in 100 patients) are:
- weight gain, increased appetite, change in blood sugar levels (diabetes) of which a symptom may be excessive thirst, increased blood fat levels
- erectile difficulties and/or loss of sex drive
- difficulty in sleeping
- dizziness, numbness or tingling sensation, sleepiness, impaired sense of taste, reduction in sensation of touch
- abnormal ECG heart tracing
- hot flushes or blushing (e.g. redness of the face or neck), increased blood pressure
- cough, shortness of breath, flu-like symptoms
- dry mouth, abdominal pain/discomfort or wind, heartburn/indigestion, constipation, more frequent passing of stools
- vomiting
- itching, hives, skin inflammation or discolouration, other type of skin conditions
- muscle cramp, pain/ache in muscles/joints, bursitis or arthritis (inflammation of joints usually accompanied by pain, swelling and/or stiffness)
- blood in the urine, abnormal frequent urination, kidney stones, abnormal urine tests (increased level of proteins in urine), a reduction in the ability of the kidneys to function properly
- fatigue, localised swelling due to the retention of fluids in the tissues (oedema)
- changes in blood chemistry or amount of blood cells (abnormal blood test results)

Rare side effects (more than 1 in 10,000 patients but less than 1 in 1,000 patients) are:
- weakness
- nervousness
- feeling thirsty
- feeling your heartbeat

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

5. HOW TO STORE ADENURIC

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the carton and the tablet blister foil after 'EXP.' The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ADENURIC contains

The active substance is febuxostat.
Each tablet contains 80 mg or 120 mg of febuxostat.

The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, magnesium stearate, hydroxypropylcellulose, croscarmellose sodium, colloidal hydrated silica.
Film-coating: Opadry II yellow, 85F42129 containing: polyvinyl alcohol, titanium dioxide (E171), macrogols 3350, talc, iron oxide yellow (E172)

What ADENURIC looks like and contents of the pack

ADENURIC film-coated tablets are pale yellow to yellow in colour and capsule shaped.
The 80 mg film-coated tablets are marked on one side with '80'. The 120 mg film-coated tablets are marked on one side with '120'.

ADENURIC is supplied in 2 blisters of 14 tablets (28 tablet pack), or 6 blisters of 14 tablets (84 tablet pack). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ipsen Manufacturing Ireland Ltd (IMIL)
Blanchardstown Industrial Park
Snugboro Road
Dublin 15
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Manufacturer
Patheon France
40 boulevard de Champaret
38300 Bourgoin Jallieu
France

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved in

Detailed information on this medicine is available on the European Medicines Agency (EMEA) website http://www.emea.europa.eu/