NURTEC®

Table of Content

Please click on either of the following links to access the required information:

1. NAME OF THE MEDICINAL PRODUCT

NURTEC® orally disintegrating tablet 75 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orally disintegrating tablet contains rimegepant sulfate, equivalent to 75 mg rimegepant.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Orally disintegrating tablet.

The orally disintegrating tablet is white to off-white, circular, diameter 14 mm and debossed with the symbol .

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NURTEC is indicated for the:

- Acute treatment of migraine with or without aura in adults;
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

4.2 Posology and method of administration

Posology

Acute treatment of migraine
The recommended dose is 75 mg rimegepant, as needed, once daily.

Prophylaxis of migraine
The recommended dose is 75 mg rimegepant every other day.

The maximum dose per day is 75 mg rimegepant.

NURTEC can be taken with or without meals.

Concomitant medicinal products
Another dose of rimegepant should be avoided within 48 hours when it is concomitantly administered with moderate inhibitors of CYP3A4 (see section 4.5).

Special populations

Elderly (aged 65 and over)
There is limited experience with rimegepant in patients aged 65 years or older. No dose adjustment is required as the pharmacokinetics of rimegepant are not affected by age (see section 5.2).

Renal impairment
No dose adjustment is required in patients with mild, moderate, or severe renal impairment. Severe renal impairment resulted in a >2-fold increase in unbound AUC but less than a 50% increase in total AUC (see section 5.2). Caution should be exercised during frequent use in patients with severe renal impairment. Rimegepant has not been studied in patients with end-stage renal disease and in patients on dialysis. Use of rimegepant in patients with end-stage renal disease (CLcr <15 mL/min) should be avoided.

Hepatic impairment
No dose adjustment is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. Plasma concentrations (unbound AUC) of rimegepant were significantly higher in subjects with severe (Child-Pugh C) hepatic impairment (see section 5.2). The use of rimegepant in patients with severe hepatic impairment should be avoided.

Paediatric population
The safety and efficacy of NURTEC in paediatric patients (<18 years of age) have not been established. No data are available.

Method of administration

NURTEC is for oral use.

The orally disintegrating tablet should be placed on the tongue or under the tongue. It will disintegrate in the mouth and can be taken without liquid.

Instructions for use/Handling

Instructions for handling the medicinal product before administration are:
- Use dry hands when opening the blister pack.
- Peel back the foil covering of one blister and gently remove the orally disintegrating tablet. Do not push the tablet through the foil.
- Take the tablet immediately after opening the blister pack. Do not store the tablet outside the blister pack for future use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Hypersensitivity reactions, including dyspnoea and rash, have occurred in less than 1% of patients treated with rimegepant in clinical studies (see section 4.8). Hypersensitivity reactions, including serious hypersensitivity, can occur days after administration. If a hypersensitivity reaction occurs, rimegepant should be discontinued and appropriate therapy should be initiated.

NURTEC is not recommended:
- in patients with severe hepatic impairment (see section 4.2);
- in patients with end-stage renal disease (CLcr <15 mL/min) (see section 4.2);

- for concomitant use with strong inhibitors of CYP3A4 (see section 4.5);
- for concomitant use with strong or moderate inducers of CYP3A4 (see section 4.5).

Medication overuse headache (MOH)
Overuse of any type of medicinal products for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of MOH should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of medicinal products for acute headache.

4.5 Interaction with other medicinal products and other forms of interaction

Rimegepant is a substrate of CYP3A4, P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) efflux transporters (see section 5.2).

CYP3A4 inhibitors

Inhibitors of CYP3A4 increase plasma concentrations of rimegepant. Concomitant administration of rimegepant with strong inhibitors of CYP3A4 (e.g., clarithromycin, itraconazole, ritonavir) is not recommended (see section 4.4). Concomitant administration of rimegepant with itraconazole resulted in a significant increase in rimegepant exposure (AUC by 4-fold and C_{max} 1.5-fold).

Concomitant administration of rimegepant with medicinal products that moderately inhibit CYP3A4 (e.g., diltiazem, erythromycin, fluconazole) may increase exposure to rimegepant. Concomitant administration of rimegepant with fluconazole resulted in increased exposures of rimegepant (AUC by 1.8-fold) with no relevant effect on C_{max}. Another dose of rimegepant within 48 hours should be avoided when it is concomitantly administered with moderate inhibitors of CYP3A4 (e.g., fluconazole) (see section 4.2).

CYP3A4 inducers

Inducers of CYP3A4 decrease plasma concentrations of rimegepant. Concomitant administration of NURTEC with strong CYP3A4 inducers (e.g., phenobarbital, rifampicin, St John's wort (*Hypericum perforatum*)) or moderate CYP3A4 inducers (e.g., bosentan, efavirenz, modafinil) is not recommended (see section 4.4). The effect of CYP3A4 induction may last for up to 2 weeks after discontinuation of the strong or moderate CYP3A4 inducer. Concomitant administration of rimegepant with rifampicin resulted in a significant decrease (AUC reduced by 80% and C_{max} by 64%) in rimegepant exposure, which may lead to loss of efficacy.

P-gp and BCRP inhibitors

Inhibitors of P-gp and BCRP efflux transporters may increase plasma concentrations of rimegepant. Another dose of NURTEC within 48 hours should be avoided when it is concomitantly administered with strong inhibitors of P-gp (e.g., cyclosporine, verapamil, quinidine). Concomitant administration of rimegepant with cyclosporine (a potent dual P-gp and BCRP inhibitor) or with quinidine (a selective P-gp inhibitor) resulted in a significant increase of similar magnitude in rimegepant exposure (AUC and C_{max} by >50%, but less than two-fold).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate human data on the developmental risk associated with the use of rimegepant in pregnancy. Animal studies demonstrate that at clinically relevant exposures rimegepant does not result in embryo-foetal death or foetal malformations. There were no developmental effects in rats at doses up to 60 mg/kg/day (exposures 46 times the human AUC at the maximum recommended human dose [MRHD] of 75 mg/day) or in rabbits at up to the highest dose tested of 50 mg/kg/day (exposures 10 times the MRHD of 75 mg/day). As a precautionary measure, it is preferable to avoid the use of NURTEC during pregnancy.

Lactation and breastfeeding

A lactation study was conducted in 12 healthy adult lactating women who were between 2 weeks and 6 months post-partum and were administered a single oral dose of rimegepant 75 mg. The results have established an average milk-to-plasma ratio of 0.20 and a relative infant dose of less than 1% of the maternal weight-adjusted dose. These data support that transfer of rimegepant into breast milk is low. There are no data on the effects of rimegepant on a breastfed infant or on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NURTEC and any potential adverse reactions on the breastfed infant from rimegepant or from the underlying maternal condition.

Fertility

Animal studies showed no clinically relevant impact on female and male fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

NURTEC has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most common adverse reaction was nausea for acute treatment (1.2%) and for migraine prophylaxis (1.4%). Most of the reactions were mild or moderate in severity. Hypersensitivity, including dyspnoea and severe rash, occurred in less than 1% of patients treated.

Tabulated list of adverse reactions

Adverse reactions are listed by MedDRA system organ class in Table 1. The corresponding frequency category for each drug reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Table 1. List of Adverse Reactions

System Organ Class	Adverse reaction	Frequency
Acute Treatment		
Gastrointestinal disorders	Nausea	Common
Immune system disorders	Hypersensitivity, including dyspnoea and severe rash	Uncommon
Prophylaxis		
Gastrointestinal disorders	Nausea	Common

Long-term safety
Long-term safety of rimegepant was assessed in two one-year, open-label extensions; 1662 patients received rimegepant for at least 6 months and 740 received rimegepant for 12 months for acute or prophylactic treatment.

Description of selected adverse reactions

Hypersensitivity reactions
Hypersensitivity, including dyspnoea and severe rash, occurred in less than 1% of patients treated in clinical studies. Hypersensitivity reactions can occur days after administration, and delayed serious hypersensitivity has occurred.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

There is limited clinical experience with rimegepant overdose. No overdose symptoms have been reported. Treatment of an overdose of rimegepant should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. No specific antidote for the treatment of rimegepant overdose is available. Rimegepant is unlikely to be significantly removed by dialysis because of high serum protein binding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, calcitonin gene-related peptide (CGRP) antagonists, ATC code: N02CD06

Mechanism of action

Rimegepant selectively binds with high affinity to the human calcitonin gene-related peptide (CGRP) receptor and antagonises CGRP receptor function.

The relationship between pharmacodynamic activity and the mechanism(s) by which rimegepant exerts its clinical effects is unknown.

Clinical efficacy: acute treatment

The efficacy of NURTEC for the acute treatment of migraine with and without aura in adults was studied in three randomised, double-blind, placebo-controlled trials (Studies 1-3). Patients were instructed to treat a migraine of moderate to severe headache pain intensity. Rescue medicinal products (i.e., NSAIDs, paracetamol, and/or an antiemetic) was allowed 2 hours after the initial treatment. Other forms of rescue medicinal products such as triptans were not allowed within 48 hours of initial treatment. Approximately 14% of patients were taking preventive medicinal products for migraine at baseline. None of the patients in Study 1 were on concomitant preventive medicinal products that act on the calcitonin gene-related peptide pathway.

The primary efficacy analyses were conducted in patients who treated a migraine with moderate to severe pain. Pain freedom was defined as a reduction of moderate or severe headache pain to no headache pain, and most bothersome symptom (MBS) freedom was defined as the absence of the self-identified MBS (i.e., photophobia, phonophobia, or nausea). Among patients who selected an MBS, the most commonly selected symptom was photophobia (54%), followed by nausea (28%), and phonophobia (15%).

In Study 1, the percentage of patients achieving headache pain freedom and MBS freedom at 2 hours after a single dose was statistically significantly greater in patients who received NURTEC compared to those who received placebo (Table 2). In addition, statistically significant effects of NURTEC compared to placebo were demonstrated for the additional efficacy endpoints of pain relief at 2 hours, sustained pain freedom from 2 to 48 hours, use of rescue medication within 24 hours, and ability to function normally at 2 hours after dosing. Pain relief was defined as a reduction in migraine pain from moderate or severe severity to mild or none. Pivotal single attack, double-blind, placebo-controlled Studies 2 & 3 were conducted in patients with migraine who received one 75 mg rimegepant bioequivalent dosage form.

Table 2. Migraine Efficacy Endpoints for Acute Treatment Studies

	Study 1		Study 2		Study 3	
	NURTEC 75 mg	**Placebo**	**Rimegepant 75 mg**	**Placebo**	**Rimegepant 75 mg**	**Placebo**
Pain Free at 2 hours						
n/N*	142/669	74/682	105/537	64/535	104/543	77/541
% Responders	21.2	10.9	19.6	12.0	19.2	14.2
Difference compared to placebo (%)	10.3		7.6		4.9	
p-value		<0.0001[a]		0.0006[a]		0.0298[a]
MBS Free at 2 hours						
n/N*	235/669	183/682	202/537	135/535	199/543	150/541
% Responders	35.1	26.8	37.6	25.2	36.6	27.7
Difference compared to placebo (%)	8.3		12.4		8.9	
p-value		0.0009[a]		<0.0001[a]		0.0016[a]
Pain Relief at 2 hours						
n/N*	397/669	295/682	312/537	229/535	304/543	247/541
% Responders	59.3	43.3	58.1	42.8	56.0	45.7
Difference compared to placebo	16.1		15.3		10.3	
p-value		<0.0001[a]		<0.0001[a]		0.0006[a]
Sustained Pain Freedom 2 to 48 hours						
n/N*	90/669	37/682	53/537	32/535	63/543	39/541
% Responders	13.5	5.4	9.9	6.0	11.6	7.2
Difference compared to placebo (%)	8.0		3.9		4.4	
p-value		<0.0001[a]		0.0181[b]		0.0130[b]

*n=number of responders/N=number of patients in that treatment group
[a] Significant p-value in hierarchical testing
[b] Nominal p-value in hierarchical testing
MBS: most bothersome symptom

Figure 1 presents the percentage of patients achieving migraine pain freedom within 2 hours following treatment in Study 1.

Figure 1: Percentage of Patients Achieving Pain Freedom within 2 Hours in Study 1

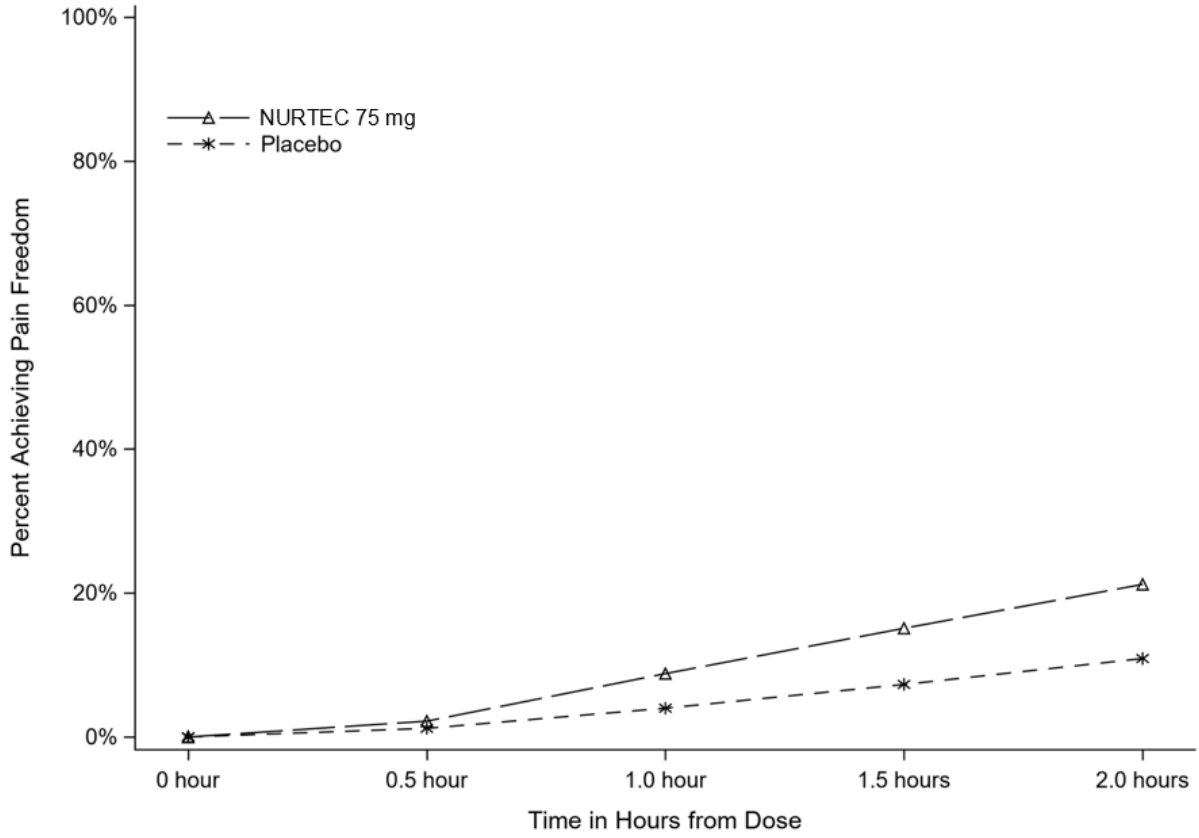
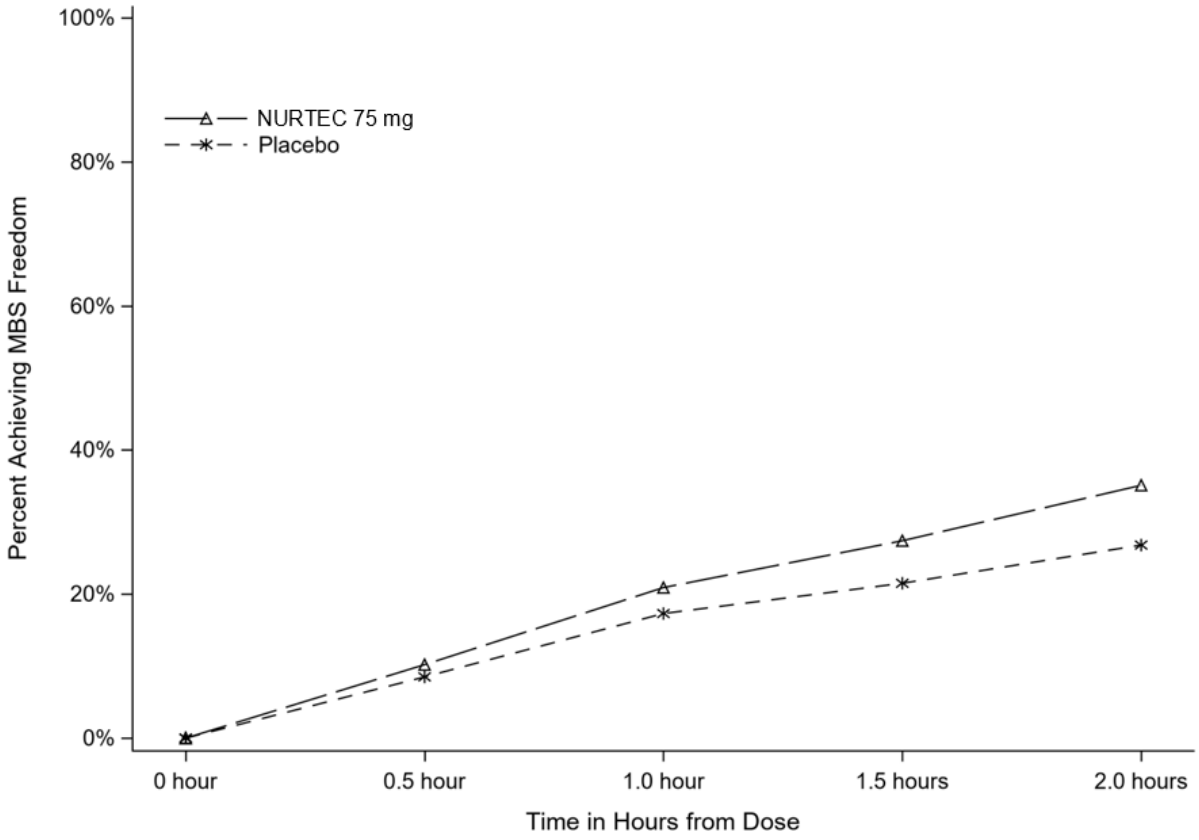


Figure 2 presents the percentage of patients achieving MBS freedom within 2 hours in Study 1.

Figure 2: Percentage of Patients Achieving MBS Freedom within 2 Hours in Study 1



The incidence of photophobia and phonophobia was reduced at 2 hours following administration of NURTEC 75 mg as compared to placebo in all 3 studies.

Clinical efficacy: prophylaxis

The efficacy of rimegepant was evaluated as a prophylactic treatment of migraine in a randomised, double-blind, placebo-controlled study (Study 4).

Study 4 included male and female adults with at least a 1-year history of migraine (with or without aura). Patients had a history of 4 to 18 migraine attacks of moderate to severe pain intensity per 4-week period within the 12 weeks prior to the screening visit. Patients experienced an average of 10.9 headache days during the 28-day observational period, which included an average of 10.2 migraine days, prior to randomisation into the study. The study randomised patients to receive rimegepant 75 mg (N=373) or placebo (N=374) for up to 12 weeks. Patients were instructed to take randomised treatment once every other day (EOD) for the 12-week treatment period. Patients were allowed to use other acute treatments for migraine (e.g., triptans, NSAIDs, paracetamol, antiemetics) as needed. Approximately 22% of patients were taking preventive medicinal products for migraine at baseline. Patients were allowed to continue in an open-label extension study for an additional 12 months.

The primary efficacy endpoint for Study 4 was the change from baseline in the mean number of monthly migraine days (MMDs) during Weeks 9 through 12 of the double-blind treatment phase. Secondary endpoints included the achievement of a ≥50% reduction from baseline in monthly moderate or severe migraine days. Rimegepant 75 mg dosed EOD demonstrated

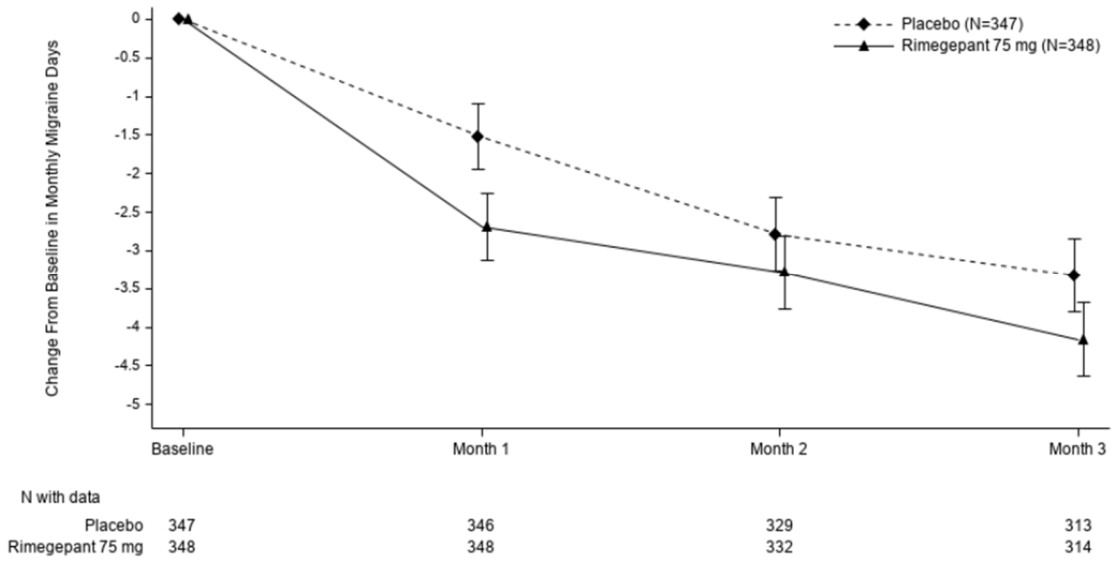
statistically significant improvements for key efficacy endpoints compared to placebo, as summarised in Table 3 and shown graphically in Figure 3.

Table 3. Key Efficacy Endpoints for Study 4

	Rimegepant 75 mg EOD	**Placebo EOD**
Monthly Migraine Days (MMD) Weeks 9 through 12	**N=348**	**N=347**
Change from baseline	-4.3	-3.5
Change compared to placebo	-0.8	
p-value	0.010[a]	
≥50% Reduction in Moderate or Severe MMDs Weeks 9 through 12	**N=348**	**N=347**
% Responders	49.1	41.5
Difference compared to placebo	7.6	
p-value	0.044[a]	

[a] Significant p-value in hierarchical testing

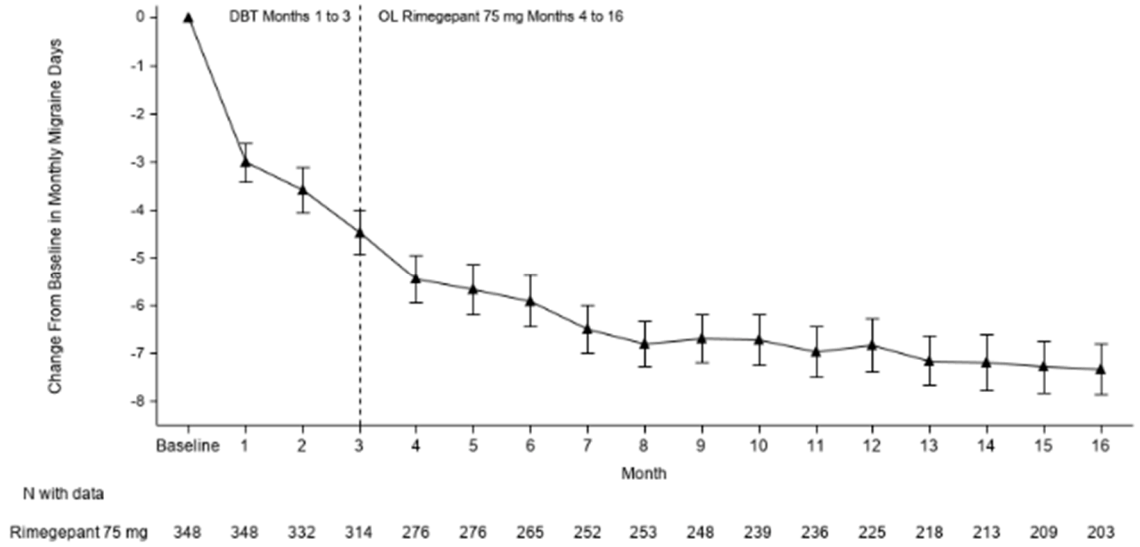
Figure 3: Change from Baseline in Monthly Migraine Days in Study 4



Long-term efficacy

Patients participating in Study 4 were allowed to continue in an open-label extension study for an additional 12 months. Efficacy was sustained for up to 1 year in an open-label study extension in which patients received rimegepant 75 mg every other day plus as needed on non-scheduled dosing days (Figure 4). A portion composed of 203 patients assigned to rimegepant completed the overall 16-month treatment period. In these patients, the overall mean reduction from baseline in the number of MMDs averaged over the 16-month treatment period was 6.2 days.

Figure 4: Longitudinal Plot of the Change in Mean Number of Monthly Migraine Days (MMDs) from the Observation Period Over Time during Double-Blind Treatment (Months 1 to 3) and during Treatment with Open-label Rimegepant (Months 4 to 16)



5.2 Pharmacokinetic properties

Absorption

Following oral administration, rimegepant is absorbed with the maximum concentration at 1.5 hours. Following a supratherapeutic dose of 300 mg, the absolute oral bioavailability of rimegepant was approximately 64%.

Effects of food
Following administration of rimegepant under fed conditions with a high-fat or low-fat meal, T_{max} was delayed by 1 to 1.5 hours. A high-fat meal reduced C_{max} by 42 to 53% and AUC by 32 to 38%. A low-fat meal reduced C_{max} by 36% and AUC by 28%. Rimegepant was administered without regard to food in clinical safety and efficacy studies.

Distribution

The steady state volume of distribution of rimegepant is 120 L. Plasma protein binding of rimegepant is approximately 96%.

Biotransformation

Rimegepant is primarily metabolised by CYP3A4 and to a lesser extent by CYP2C9. Rimegepant is primarily eliminated in unchanged form (~77% of the dose) with no major metabolites (i.e., >10%) detected in plasma.

Based on *in vitro* studies, rimegepant is not an inhibitor of CYP1A2, 2B6, 2C9, 2C19, 2D6, or UGT1A1 at clinically relevant concentrations. However, rimegepant is a weak inhibitor of CYP3A4 with time-dependent inhibition. Rimegepant is not an inducer of CYP1A2, CYP2B6, or CYP3A4 at clinically relevant concentrations.

Elimination

The elimination half-life of rimegepant is approximately 11 hours in healthy subjects. Following oral administration of [^{14}C]-rimegepant to healthy male subjects, 78% of the total radioactivity was recovered in faeces and 24% in urine. Unchanged rimegepant is the major single component in excreted faeces (42%) and urine (51%).

Transporters
In vitro, rimegepant is a substrate of P-gp and BCRP efflux transporters. Inhibitors of P-gp and BCRP efflux transporters may increase plasma concentrations of rimegepant (see section 4.5).

Rimegepant is not a substrate of OATP1B1 or OATP1B3. Considering its low renal clearance, rimegepant was not evaluated as a substrate of the OAT1, OAT3, OCT2, MATE1, or MATE2-K.

Rimegepant is not an inhibitor of P-gp, BCRP, OAT1, or MATE2-K at clinically relevant concentrations. It is a weak inhibitor of OATP1B1 and OAT3.

Rimegepant is an inhibitor of OATP1B3, OCT2, and MATE1. Concomitant administration of rimegepant with metformin, a MATE1 transporter substrate, resulted in no clinically significant impact on either metformin pharmacokinetics or on glucose utilisation. No clinical drug interactions are expected for rimegepant with OATP1B3 or OCT2, at clinically relevant concentrations.

Linearity/non-linearity

Rimegepant exhibits greater than dose proportional increases in exposure following single oral administration, which appears to be related to a dose-dependent increase in bioavailability.

Age, sex, weight, race, ethnicity

No clinically significant differences in the pharmacokinetics of rimegepant were observed based on age, sex, race/ethnicity, body weight, migraine status, or CYP2C9 genotype.

Renal impairment

In a dedicated clinical study comparing the pharmacokinetics of rimegepant in subjects with mild (estimated creatinine clearance [CLcr] 60-89 mL/min), moderate (CLcr 30-59 mL/min), and severe (CLcr 15-29 mL/min) renal impairment to that of normal subjects (healthy pooled control), a less than 50% increase in total rimegepant exposure was observed following a single 75 mg dose. The unbound AUC of rimegepant was 2.57-fold higher in subjects with severe renal impairment. NURTEC has not been studied in patients with end-stage renal disease (CLcr <15 mL/min).

Hepatic impairment

In a dedicated clinical study comparing the pharmacokinetics of rimegepant in subjects with mild, moderate, and severe hepatic impairment to that of normal subjects (healthy matched control), the exposure of rimegepant (unbound AUC) following a single 75 mg dose was 3.89-fold higher in subjects with severe impairment (Child-Pugh class C). There were no clinically meaningful differences in the exposure of rimegepant in subjects with mild (Child-Pugh class A) and moderate hepatic impairment (Child-Pugh class B) compared to subjects with normal hepatic function.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for rimegepant in humans based on conventional studies of safety pharmacology, repeat-dose toxicity, genotoxicity, phototoxicity, reproduction or development, or carcinogenic potential.

Rimegepant-related effects at higher doses in repeat-dose studies included hepatic lipidosis in mice and rats, intravascular haemolysis in rats and monkeys, and emesis in monkeys. These findings were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use (≥12 times [mice] and ≥49 times [rats] for hepatic lipidosis, ≥95 times [rats] and ≥9 times [monkeys] for intravascular haemolysis, and ≥37 times for emesis [monkeys]).

Oral administration of rimegepant to male and female rats prior to and during mating, and continuing in females to gestation day 7, resulted in reduced fertility at the highest dose (150 mg/kg/day) tested.

The no-effect dose for impairment of fertility and early embryonic development in rats of 60 mg/kg/day was associated with plasma drug exposures (AUC) approximately 30 times that in humans at the MRHD of 75 mg/day.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Mannitol (E421)
Mint flavour
Sucralose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Refer to outer carton.

6.4 Special precautions for storage

Store below 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Unit dose blisters made of polyvinyl chloride (PVC), oriented polyamide (OPA) and aluminium foil and sealed with a peelable aluminium foil.

Pack sizes:
Unit dose 2 x 1 orally disintegrating tablets.
Unit dose 8 x 1 orally disintegrating tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURER

Catalent UK Swindon Zydis Limited
Frankland Road, Blagrove,
Swindon, SN5 8RU,
United Kingdom

NUR-SIN-0823/0
Date of last revision: August 2023

Package leaflet: Information for the patient
NURTEC® orally disintegrating tablet 75 mg
rimegepant

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 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 NURTEC is and what it is used for

NURTEC contains the active ingredient rimegepant, that stops the activity of a substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP. Rimegepant attaches to the receptor for CGRP, reducing the ability of CGRP to also attach to the receptor. This reduces the activity of CGRP and has two effects:
1) it can stop an active migraine attack, and
2) it can decrease the number of migraine attacks that occur when taken preventively.

NURTEC is used to treat and prevent migraine attacks in adults.

2. What you need to know before you take NURTEC

Do not take NURTEC
- if you are allergic to rimegepant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking NURTEC, if any of the following applies to you:
- if you have severe liver problems
- if you have reduced kidney function or are on kidney dialysis

During treatment with NURTEC, stop taking this medicine and tell your doctor immediately:

- if you experience any symptoms of an allergic reaction, e.g., trouble breathing or severe rash. These symptoms can occur several days after administration.

Children and adolescents
NURTEC should not be given to children and adolescents under 18 years of age because it has not yet been studied in this age group.

Other medicines and NURTEC
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines may affect the way NURTEC works or NURTEC may affect how other medicines work.

The following is a list of examples of medicines that should be avoided when taking NURTEC:
- itraconazole and clarithromycin (medicines used to treat fungal or bacterial infections).
- ritonavir and efavirenz (medicines to treat HIV infections).
- bosentan (a medicine used to treat high blood pressure).
- St. John's wort (a herbal remedy used to treat depression).
- phenobarbital (a medicine used to treat epilepsy).
- rifampicin (a medicine used to treat tuberculosis).
- modafinil (a medicine used to treat narcolepsy).

Do not take NURTEC more than once every 48 hours with:
- fluconazole and erythromycin (medicines used to treat fungal or bacterial infections).
- diltiazem, quinidine, and verapamil (medicines used to treat an abnormal heart rhythm, chest pain (angina) or high blood pressure).
- cyclosporine (a medicine used to prevent organ rejection after an organ transplant).

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is preferable to avoid the use of NURTEC during pregnancy as the effects of this medicine in pregnant women are not known.

If you are breastfeeding or are planning to breastfeed, talk to your doctor or pharmacist before using this medicine. You and your doctor should decide if you will use NURTEC while breastfeeding.

Driving and using machines
NURTEC is not expected to affect your ability to drive or use machines.

3. How to take NURTEC

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

How much to take
For prevention of migraine, the recommended dose is one orally disintegrating tablet (75 mg rimegepant) every other day.

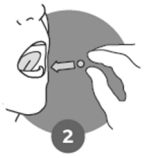
For treatment of a migraine attack once it has started, the recommended dose is one orally disintegrating tablet (75 mg rimegepant), as needed, once daily.

The maximum daily dose is one orally disintegrating tablet (75 mg rimegepant) per day.

How to take this medicine
NURTEC is for oral use.
The orally disintegrating tablet can be taken without drink or water.

Instructions:

Use dry hands when opening the blister pack. Peel back the foil covering of one blister and gently remove the orally disintegrating tablet. Do **not** push the orally disintegrating tablet through the foil.



As soon as the blister is opened, remove the orally disintegrating tablet and place it on or under the tongue, where it will dissolve. No drink or water is needed.

Do not store the orally disintegrating tablet outside the blister for future use.

If you take more NURTEC than you should
Talk to your doctor or pharmacist or go to a hospital straight away. Take the medicine pack and this leaflet with you.

If you forget to take NURTEC
If you take NURTEC for the prevention of migraine and you miss a dose, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop using NURTEC and contact your doctor straight away if you have signs of an allergic reaction such as severe rash or shortness of breath. Allergic reactions with NURTEC are uncommon (may affect up to 1 in 100 people).

A common side effect (may affect up to 1 in 10 people) is nausea.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NURTEC

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 carton and the blister after EXP.

Store below 30°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NURTEC contains
- The active substance is rimegepant. Each orally disintegrating tablet contains 75 mg rimegepant (as sulfate).
- The other ingredients are: gelatin, mannitol, mint flavour, and sucralose.

What NURTEC looks like and contents of the pack
NURTEC 75 mg orally disintegrating tablet is white to off-white, circular, and debossed with the symbol .

Pack sizes:
- 2 x 1 orally disintegrating tablets.
- 8 x 1 orally disintegrating tablets.

Not all pack sizes may be marketed.

NUR-SIN-0823/PIL/0
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