Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

AERINEX 70 mg/ml solution for injection in a single-use pre-filled syringe
AERINEX 140 mg/ml solution for injection in a single-use pre-filled syringe

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Erenumab (genetically engineered using Chinese hamster ovary cells).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe or pre-filled pen for subcutaneous use:
1 pre-filled syringe or 1 pre-filled pen of 1 ml contains 70 mg erenumab in 1 ml (70 mg/ml) solution for injection.

1 pre-filled syringe or 1 pre-filled pen of 1 ml contains 140 mg erenumab in 1 ml (140 mg/ml) solution for injection.

The solution is clear to opalescent, colourless to light yellow, and practically free from particles.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prophylactic treatment of migraine in adults, where indicated.

4.2. Posology and method of administration

The indication for therapy must be established by a physician with experience in migraine treatment and the patient must be monitored by this physician throughout treatment. Continuation of therapy should be re-evaluated in the event of a lack of therapeutic response or after a maximum of 12 months.

To ensure traceability of medicinal products produced using biotechnology, it is recommended that the trade name and batch number be documented at every treatment.

The recommended dose of Aerinex is 70 mg by subcutaneous injection once monthly.

In patients exhibiting an inadequate response to this dosage it may be increased to 140 mg once monthly provided that this yields an improved response.

<u>Patients with hepatic impairment</u>
No clinical studies have been conducted in patients with hepatic impairment. No dose adjustment is recommended in patients with hepatic impairment as erenumab, a human immunoglobulin G, is not metabolised by cytochrome P450 enzymes and the liver is not a major pathway for its clearance.

Patients with renal impairment
No dose adjustment is necessary in patients with mild to moderate renal impairment. Population pharmacokinetic analysis of integrated data from the Aerinex clinical trials showed no difference between patients with mild or moderate renal impairment and those with normal renal function with regard to the pharmacokinetics of erenumab. Patients with severe renal impairment (eGFR <30 ml/min/1.73 m^2) have not been studied.

Elderly patients
Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether such patients respond differently from younger patients. A dose adjustment is not required as the pharmacokinetics of erenumab are not affected by age.

Children and adolescents
The safety and efficacy of Aerinex in children and adolescents have not been studied. Aerinex must therefore not be used in this age group.

Late administration
If a scheduled dose is forgotten, it should be administered as soon as possible and further injections should be scheduled monthly from the date of the last injection.

Method of administration
Aerinex is intended for patient self-administration into the abdominal wall or thigh. Injection sites should be rotated and injections should not be given into areas where the skin is tender, injured, red or hard. The injections may also be administered into the upper arm by another person.

The person administering the product must have been instructed in the administration technique by a professional. Detailed instructions for use can be found in the patient information (package leaflet).

4.3. Contraindications

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

4.4. Special warnings and special precautions for use

Hypersensitivity reactions
Serious hypersensitivity reactions, including rash, angioedema and anaphylactoid reactions, have been reported with Aerinex in the post-marketing setting. These reactions may occur within minutes, but some may not become apparent until more than one week after treatment. If a severe or serious hypersensitivity reaction occurs, administration of Aerinex must be discontinued immediately and appropriate therapy initiated.

Constipation with severe complications
Constipation with severe complications may occur during Aerinex treatment (see section 4.8).
Patients taking Aerinex should therefore be monitored for signs of severe constipation and treated as clinically indicated.

Co-administration of medicinal products associated with decreased gastrointestinal motility may increase the risk of severe constipation and potential complications.

Patients with severe cardiovascular disorders

Patients with certain severe cardiovascular diseases were excluded from participation in the clinical studies. No safety data are available for these patients.

Latex-sensitive patients
The removable cap of the Aerinex pre-filled syringe and the Aerinex pre-filled pen contains dry natural rubber latex, which may cause allergic reactions in individuals sensitive to latex.

Polysorbate 80
This medicinal product contains 0.1 mg of polysorbate 80 in each ml which is equivalent to 0.004 mg/kg.

Sodium
This medicine contains less than 1 mmol (23 mg) of sodium per pre-filled syringe/pre-filled pen (70 mg/ml, 140 mg/ml), making it practically “sodium-free”.

4.5. Interaction with other medicinal products and other forms of interaction

In an open-label pharmacokinetic drug interaction study of Aerinex and a combined oral contraceptive in healthy female subjects erenumab (140 mg subcutaneously [s.c.], single dose) did not affect the pharmacokinetics of a combined oral contraceptive containing ethinylestradiol and norgestimate.

In a randomised, double-blind, placebo-controlled study in healthy subjects co-administration of erenumab (140 mg intravenously [i.v.], single dose) and sumatriptan had no effect on resting blood pressure compared with sumatriptan alone. Aerinex had no effect on the pharmacokinetics of sumatriptan. Erenumab is not metabolised by cytochrome P450 enzymes. Therefore, interactions with concomitant medications that are substrates, inducers or inhibitors of cytochrome P450 enzymes are unlikely.

4.6. Fertility, pregnancy and lactation

Pregnancy
There are insufficient data on the use of Aerinex in pregnant women. Animal studies have not shown any direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).
Animal studies are not always predictive of human response; therefore, it is not known whether Aerinex can cause fetal harm when administered to a pregnant woman. Aerinex should not be used during pregnancy unless clearly necessary.

Lactation
It is not known whether Aerinex passes into human breast milk. Since many medicinal products, including antibodies, are excreted in breast milk, a risk to newborns/infants cannot be ruled out. Therefore, a decision should be made whether to discontinue breast-feeding or discontinue Aerinex, taking into account the potential benefit of Aerinex to the mother and the potential benefit of breast-feeding to the infant.

Fertility
No data are available on the effect of Aerinex on human fertility. Animal studies have not shown any evidence of harmful effects on fertility (see section 5.3).

4.7. Effects on ability to drive and use machines

No relevant studies have been conducted. However, based on the available data Aerinex is not expected to affect the ability to drive and use machines.

4.8. Undesirable effects

Data from two phase 3 and two phase 2 clinical studies on migraine were pooled to evaluate the safety of Aerinex in comparison to placebo up to 12 weeks after treatment initiation.

A total of 2,656 patients took part in the placebo-controlled studies. 1,613 patients received Aerinex and 1,043 patients received placebo. Of these, 893 patients received a 70 mg dose of Aerinex and 507 patients received a 140 mg dose of Aerinex.

The overall safety population, including the patients in the open-label extension phase with Aerinex, comprised 2,537 patients (3040.2 patient-years) who received at least one dose of Aerinex: 2,280 patients were treated for at least 6 months, 1,320 patients were treated for at least 12 months and 217 patients were treated for 5 years. The overall safety profile of Aerinex remained consistent throughout the 5-year open-label treatment phase.

Frequencies are defined as follows:
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), "frequency not known" (cannot be estimated from available data).

Immune system disorders
Frequency not known: Hypersensitivity reactions, including rash, angioedema and anaphylactoid reactions (see section 4.4).

Gastrointestinal disorders
Common: Constipation (see section 4.4 and "Description of specific adverse effects and additional information").

Skin and subcutaneous tissue disorders
Common: Pruritus

Musculoskeletal and connective tissue disorders
Common: Muscle spasms

General disorders and administration site conditions
Common: Injection site reactions (pain, erythema or pruritus)

Post-marketing adverse effects

Immune system disorders
Frequency not known: Hypersensitivity reactions, including rash, angioedema and anaphylactoid reactions (see section 4.4).

Vascular disorders
Frequency not known: Hypertension (see "Description of specific adverse effects and additional information")

Gastrointestinal disorders
Frequency not known: Cases of constipation with severe complications have been reported (see section 4.4 and "Description of specific adverse effects and additional information").
Frequency not known: Mouth ulcers (e.g. stomatitis, mouth ulceration, oral mucosal blistering)

Skin and subcutaneous tissue disorders
Frequency not known: Alopecia
Frequency not known: Rash (e.g. papular rash, exfoliative rash, erythematous rash, urticaria, blistering)

Description of specific adverse effects and additional information
Immunogenicity
In the four clinical studies on migraine prophylaxis (20120178, 20120295, 20120296 and 20120297) the incidence of anti-erenumab antibody development during the double-blind treatment phase was 6.3% (56/884) among patients treated with 70 mg Aerinex (3 of whom showed in vitro neutralising activity) and 2.6% (13/504) among patients treated with 140 mg Aerinex (none of whom showed in vitro neutralising activity). Including overall data from the 4 studies until the open-label extension phase, the incidence of anti-erenumab antibody development was 8.0% (185/2,303) among patients who only received 70 mg or 140 mg Aerinex throughout the entire study (8 of whom had in vitro neutralising activity). In an open-label study with up to 256 weeks of treatment the incidence of anti-erenumab antibody development was 11.0% (25/225) among patients who only received 70 mg or 140 mg Aerinex throughout the entire study (2 of whom showed in vitro neutralising activity). Anti-erenumab antibody development had no impact on the efficacy or safety of Aerinex.

The incidence of anti-drug antibodies (ADAs) is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralising antibody) positivity in an assay may be influenced by several factors such as assay methodology, sample handling, timing of sample collection, concomitant medications and underlying disease. For this reason comparison of the incidence of antibodies to erenumab with the incidence of antibodies to other medicinal products may be misleading.

Constipation
Constipation was one of the most common adverse effects in clinical studies reported during the 12-week placebo-controlled phase of clinical studies (up to 3%).

All cases were mild or moderate in severity. In the post-marketing setting cases of constipation with serious complications were also reported. Some cases necessitated hospitalisation, including surgery. In most patients constipation occurred after the first dose of Aerinex, but constipation was also reported later on in treatment. Aerinex therapy was interrupted in most reported cases of severe constipation. Many of these cases were reported in patients who had a history of constipation or were simultaneously using medicinal products associated with decreased gastrointestinal motility (see section 4.4).

Hypertension
Post-marketing cases of hypertension and worsening of pre-existing hypertension have been reported. Many of these cases were reported in patients with pre-existing hypertension or risk of hypertension.
Reporting suspected adverse effects after authorisation of the medicinal product is very important. It allows continued monitoring of the risk-benefit ratio of the medicinal product.

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 via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9. Overdose

There is no experience with Aerinex overdose in clinical studies. Doses of up to 280 mg s.c. have been administered in clinical studies with no evidence of dose-limiting toxicity.

In the event of an overdose the patient should be treated symptomatically and supportive measures instituted as required.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, antimigraine preparations, ATC code: N02CD01

Mechanism of action

Erenumab is a human monoclonal antagonist antibody against the calcitonin gene-related peptide (CGRP) receptor with no significant pharmacological activity at adrenomedullin, calcitonin and amylin receptors and no agonist activity at the CGRP receptor.

CGRP is a neuropeptide that modulates nociceptive signalling and a vasodilator that has been associated with migraine pathophysiology.

The CGRP receptor is located at sites that are relevant to migraine pathophysiology. Erenumab potently and specifically competes with CGRP for binding to the CGRP receptor, thereby inhibiting CGRP function at the CGRP receptor.

In a randomised, double-blind, placebo-controlled study (20140254) to evaluate the efficacy of Aerinex (140 mg i.v., single dose) in patients with stable angina, Aerinex did not decrease exercise duration during a treadmill test compared to placebo and did not aggravate myocardial ischaemia.

Clinical efficacy

Chronic migraine

Study 20120295

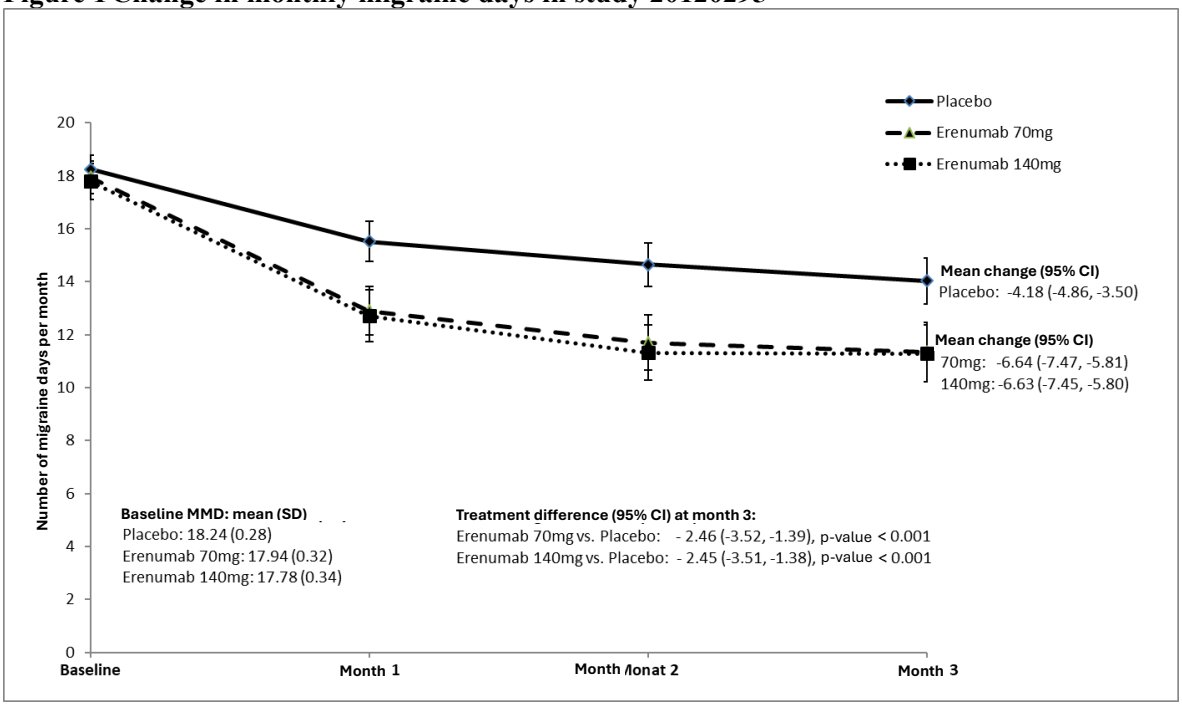
Aerinex was evaluated for prophylaxis of chronic migraine in a randomised, multicentre, 12-week, placebo-controlled, double-blind study. A total of 667 patients with a history of migraine with or without aura (≥15 headache days per month with ≥8 migraine days per month) were randomised to receive placebo (n=286), 70 mg Aerinex (n=191) or 140 mg Aerinex (n=190) by subcutaneous injection every 4 weeks for 12 weeks.

The mean migraine frequency at baseline was approximately 18 migraine days per month and was similar across treatment groups. Patients were allowed to use acute headache treatments such as triptans, ergotamine derivatives and NSAIDs during the study.

The median age of the patients was 43 years (range: 18-66 years); 83% were female and 94 % were white. Patients with pre-existing myocardial infarction, stroke, transient ischaemic attacks, unstable angina pectoris, coronary artery bypass surgery or other revascularisation procedures within 12 months prior to screening were excluded from study 20120295.

The primary outcome variable was the change in monthly migraine days from baseline at month 3. Secondary outcome variables included the achievement of a 50-100% reduction in monthly migraine days from baseline (≥50% responders) and change from baseline in monthly acute migraine-specific medication days.

Figure 1 Change in monthly migraine days in study 20120295



Least-square means and 95% confidence intervals are presented.
The p-value for the difference in least-square means between erenumab and placebo assessed at month 3 (primary outcome variable) was <0.001.

Table 1 Changes from baseline in efficacy and patient-reported outcome variables at week 12 in study 20120295

	70 mg Aerinex (n=188)	*140 mg Aerinex (n=187)*	*Placebo (n=281)*	*Treatment difference/ odds ratio[c] (95% CI)*	*p-value[a]*
≥50% MMD responders[c] Percent (%)	39.9	41.2	23.5	OR[d] 70 mg: 2.18 (1.46, 3.27) 140 mg: 2.34 (1.56, 3.51)	<0.001
Monthly acute migraine-specific medication days[e] Mean change[b] (95% CI)	-3.45 (-4.02, -2.87)	-4.13 (-4.70, -3.56)	-1.58 (-2.05; -1.11)	TD 70 mg: -1.86 (-2.60, -1.13) 140 mg: -2.55 (-3.28; -1.82)	<0.001

TD = treatment difference, CI = confidence interval; MMD = monthly migraine days, OR = odds ratio

[a] All p-values are reported as unadjusted p-values that are statistically significant after adjustment for multiple comparisons.

[b] Least-squares mean change from baseline at month 3, treatment difference and p-value are based on a linear mixed-effects model taking into account treatment group, baseline monthly value, stratification factors (region [North America vs Europe] and medication overuse [presence vs absence]), scheduled visit and the interaction between treatment group and scheduled visit, without any imputation for missing data.

[c] Responders are defined as patients who achieve a ≥50% reduction from baseline in monthly migraine days.

[d] Odds ratio and p-value for ≥50% responders at month 3 are based on a stratified Cochran-Mantel-Haenszel test after missing data were imputed as non-response.

[e] Migraine-specific medications include triptans and ergotamine derivatives.

Episodic migraine

Study 20120296, STRIVE

Study 20120296 was a randomised, multicentre, 24-week, placebo-controlled, double-blind study evaluating Aerinex for prophylaxis of episodic migraine. A total of 955 patients with a history of migraine with or without aura for a duration of ≥12 months and 4-14 migraine days per month were randomised to receive either 70 mg Aerinex (n=317), 140 mg Aerinex (n=319) or placebo (n=319) by subcutaneous injection every 4 weeks for 24 weeks.

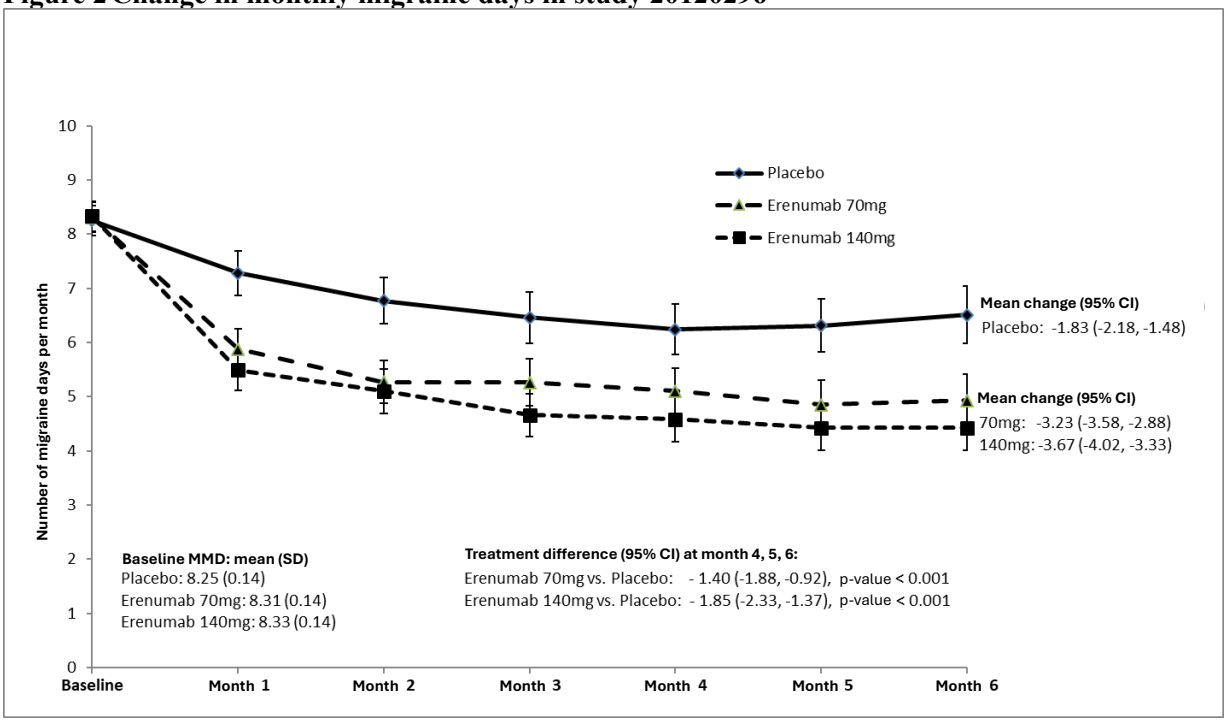
The mean migraine frequency at baseline was approximately 8 migraine days per month and was similar across treatment groups. Patients were allowed to use acute headache treatments such as triptans, ergotamine derivatives and NSAIDs during the study.

The median age of the patients was 42 years (18-65 years), 85% were female and 89% were white. Patients with medication overuse, pre-existing myocardial infarction, stroke, transient ischaemic attacks, unstable angina pectoris, coronary artery bypass surgery or other revascularisation procedures within 12 months prior to screening were excluded from study 20120296.

The primary endpoint was the change from baseline in monthly migraine days at months 4-6. Secondary endpoints included the achievement of a 50-100% reduction in mean monthly migraine days from baseline (≥50% responders) and change from baseline in mean monthly acute migraine-specific medication days.

Differences from placebo were observable as early as after one month.

Figure 2 Change in monthly migraine days in study 20120296[a]



[a] Least-square means and 95% confidence intervals are presented.

The p-value for the difference in least-square means between erenumab and placebo as the average over months 4, 5, and 6 (primary outcome variable) was <0.001.

Table 2 Changes from baseline in efficacy and patient-reported outcome variables at weeks 13-24 in study 20120296

	70 mg Aerinex (n=312)	*140 mg Aerinex* (n=318)	*Placebo* (n=316)	*Treatment difference/odds ratio* (95% CI)	*p-value*[a]
≥50% MMD responders[c] Percent (%)	43.3	50.0	26.6	OR[d] 70 mg: 2.13 (1.52, 2.98) 140 mg: 2.81 (2.01, 3.94)	<0.001
Monthly acute migraine-specific medication days[e] Mean change[b] (95% CI)	-1.13 (-1.34, -0.92)	-1.61 (-1.83; -1.40)	-0.20 (-0.41; 0.02)	TD 70 mg: -0.94 (-1.23, -0.64) 140 mg: -1.42 (-1.71; -1.12)	<0.001

TD = treatment difference, CI = confidence interval; MMD = monthly migraine days, OR = odds ratio

[a] All p-values are reported as unadjusted p-values that are statistically significant after adjustment for multiple comparisons.

[b] Least-squares mean change from baseline at months 4-6, treatment difference and p-value are based on a linear mixed-effects model taking into account treatment group, baseline value, stratification factors (region [North America vs rest of world], prior prophylactic medication use [no use, prior use only, concomitant use]), scheduled visit and the interaction between treatment group and scheduled visit, without any imputation for missing data.

[c] Responders are defined as patients who achieve a ≥50% reduction from baseline in monthly migraine days.

[d] Odds ratio and p-value for ≥50% responders at months 4-6 are based on a stratified Cochran-Mantel-Haenszel test after missing data were imputed as non-response.

[e] Migraine-specific medications include triptans and ergotamine derivatives.

Long-term follow-up study

Following a placebo-controlled study 383 patients, in an open-label treatment phase over 5 years, initially received 70 mg erenumab (median exposure: 2.0 years), of which 250 patients increased their dose to 140 mg (median exposure: 2.7 years). 214 completed the open-label treatment phase of 5 years. Of the 383 patients, 168 (43.9%) discontinued treatment, with the most common reasons being patient request (84 patients; 21.9%), adverse events (19 patients; 5.0%), lost to follow-up (14 patients; 3.7%) and lack of efficacy (12 patients; 3.1%). The results show that efficacy was sustained for up to 5 years in the open-label treatment phase of the study.

5.2. Pharmacokinetic properties

Absorption

Erenumab exhibits non-linear kinetics as a result of binding to the CGRP receptor. Subcutaneous administration of a 70 mg and 140 mg dose to healthy subjects resulted in a C_{max} mean (standard deviation [SD]) of 6.1 [2.1] and 15.8 [4.8] µg/ml and an AUC_{last} mean [SD] of 159 [58] and 505 [139] day*µg/ml.

Serum trough levels were increased less than 2 fold following subcutaneous administration of 70 mg and 140 mg doses every 4 weeks (C_{min} [SD] 5.7 [3.1] and 6.2 [2.9] µg/ml at a 70 mg dose and C_{min} [SD] 12.8 [6.5] and 14.9 [6.5] µg/ml at a 140 mg dose in episodic and chronic migraine patients, respectively) and approached steady state after 12 weeks of administration.

Following administration of a single subcutaneous dose of 70 mg or 140 mg Aerinex to healthy adults the median time to peak serum concentrations was around 6 days. The absolute bioavailability estimated from the population pharmacokinetic analysis was 82%.

Distribution
Following a single 140 mg intravenous dose the mean volume of distribution (SD) during the terminal phase (Vz) was estimated to be 3.86 (0.77) litres.

Metabolism
The effective half-life of Aerinex estimated based on the population pharmacokinetic analysis is 28 days.

Elimination
Two elimination phases were observed for Aerinex. At low concentrations Aerinex is eliminated mainly through saturable binding to target (CGRP R) and at higher concentrations largely via a non-specific, non-saturable proteolytic elimination pathway.

Linearity/non-linearity
Following subcutaneous monthly administration of doses of 70 and 140 mg the pharmacokinetics of Aerinex are linear within the dosing interval, with serum concentrations increasing dose-proportionally.

Pharmacokinetics in special patient populations
Population pharmacokinetic (PK) analysis showed that the pharmacokinetics of erenumab were not affected by age, gender, ethnicity, migraine subtype (episodic or chronic migraine) or estimated glomerular filtration rate (eGFR) in any approved patient population. Patients with severe renal impairment (eGFR <30 ml/min/1.73 m^2) have not been studied.

5.3. Preclinical safety data

Preclinical data based on conventional studies of safety pharmacology, repeated-dose toxicity and reproductive and developmental toxicity reveal no special hazard for humans.

Mutagenicity
The mutagenic potential of Aerinex has not been studied. However, it is unlikely that monoclonal antibodies would alter DNA or chromosomes.

Carcinogenicity
Carcinogenicity studies have not been conducted with Aerinex. Aerinex is not pharmacologically active in rodents, but exhibits biological activity in cynomolgus monkeys; however, this species is not an appropriate model for investigation of tumorigenic risk.

Reproductive toxicity
In a reproduction study in cynomolgus monkeys (ePPND, enhanced pre- and postnatal development study) no effects were found on pregnancy and embryo-fetal or postnatal development (up to 6 months of age) when erenumab was administered during pregnancy at doses leading to exposure levels 17-fold higher than those reached in patients treated with 140 mg once monthly (based on serum AUC). Erenumab was detectable at birth in the serum of the newborn monkeys, confirming that erenumab, like other IgG antibodies, crosses the placental barrier.

Additional data (local toxicity, phototoxicity, immunotoxicity)
In chronic toxicity studies in sexually mature monkeys administered a dose of up to 150 mg/kg Aerinex subcutaneously twice weekly for up to 6 months no adverse effects were determined at systemic exposures up to 123-fold higher than those reached on administration of the clinical dose of 140 mg every 4 weeks (based on serum AUC). There were also no adverse effects on surrogate markers of fertility (anatomical pathology or histopathology changes in reproductive organs) in these studies.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sucrose
Polysorbate 80
Sodium hydroxide equivalent to 0.2 mg sodium/ml
Glacial acetic acid
Water for injections

6.2. Incompatibilities

Given the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf life

36 months.

Do not use after the expiry date (= EXP) printed on the container. The pre-filled syringe and pre-filled pen are for single use only.

6.4. Special precautions for storage

Store in a refrigerator (2-8°C).
Store the pre-filled syringe or pre-filled pen in the original pack in the outer carton to protect the contents from light.
Keep out of the reach and sight of children.

After Aerinex has been removed from the refrigerator, it can be stored at room temperature (15 -25°C) but must then be used within 7 days. Aerinex must not be re-refrigerated after it has reached room temperature.

6.5. Nature and contents of container and special equipment for use, administration or implantation

Solution for injection in pre-filled syringe: 1 pre-filled syringe containing 70 mg or 140 mg.
Solution for injection in pre-filled pen: 1 pre-filled pen containing 70 mg or 140 mg.

6.6. Special precautions for disposal and other handling

The fluid should be inspected before use. Do not inject if the fluid is cloudy, distinctly yellow or contains flakes or particles.

Prior to subcutaneous administration leave Aerinex to stand at room temperature for at least 30 minutes.

Do not shake the product.

7. MARKETING AUTHORISATION HOLDER

Novartis Overseas Investments AG

Lichtstrasse 35
4056 Basel
Switzerland

Manufacturer
Amgen Manufacturing Limited
State Road 31, Km 24.6 Juncos
Puerto Rico 00777-4060
United States (USA)

Releaser
Novartis Manufacturing NV
Rijksweg 14
2870 Puurs-Sint-Amands
Belgium

8. MARKETING AUTHORISATION NUMBER

Aerinex 70 mg/ml solution for injection
Swissmedic: 66748
Ethiopia: ET/04791/MRN/2025
Ghana: FDA/BL/243-01001
Kenya: H2021/CTD8462/16505

Aerinex 140 mg/ml solution for injection
Swissmedic: 66748
Ethiopia: ET/05194/MRN/2025
Ghana: FDA/BL/243-01002

9. DATE OF FIRST AUTHORISATION

Aerinex 70 mg/ml solution for injection
Ethiopia: 15 May 2020
Ghana: 14 January 2021
Kenya: 25 October 2019

Aerinex 140 mg/ml solution for injection
Ethiopia: 17 March 2021
Ghana: 14 January 2021

10. DATE OF REVISION OF THE TEXT

September 2022 (Swissmedic)