

SKEDULERINGSTATUS

SUID AFRIKA: S3

NAMIBIË: NS2

EIENDOMSNAAM (en doseervorm):
FLAMARYX 7,5 mg (tablet)
FLAMARYX 15 mg (tablet)

SAMESTELLING:
FLAMARYX 7,5 mg: Elke onbedekte tablet bevat 7,5 mg meloksikam. Bevat suiker: 23,50 mg laktosemonohidraat.
FLAMARYX 15 mg: Elke onbedekte tablet bevat 15 mg meloksikam. Bevat suiker: 20,00 mg laktosemonohidraat.

Die ander bestanddele is mikrokristallyne sellulose, krospovidoon, laktosemonohidraat, magnesiumstearaat, povidoon, anhidriese kolloïdale silika en natriumsitraat.

FARMAKOLOGIESE KLASSIFIKASIE:

A 3.1 Antirumatiese middels (anti-inflammatoriese middels).

FARMAKOLOGIESE WERKING:

Meloksikam, 'n oksikam (enoliese suur) derivaat, is 'n nie-steroïed anti-inflammatoriese middel (NSAIM) met analgetiese, antipiretiese en anti-inflammatoriese aktiwiteite. Die werking van meloksikam is verwant aan inhibisie van die ensiem siklo-oksigenase (COX), wat tot gevolg het die verminderde formasie van prostaglandiene (mediators van inflammasie) en tromboksanes. 'n Selektiewe COX-2 inhiberende (anti-inflammatoriese effek) *in vitro* in verhouding tot COX-1 is gedemonstreer. Inhibisie van COX-1 (gastrointestinaal, renaal en plaatjie effekte) *in vivo* kom voor. Dit word gesuggereer dat die omvang van inhibisie van COX-1 *in vivo* 'n funksie is van dosis en inter-individuele vaneerbaarheid van meloksikam konsentrasies.

Farmakokinetika:

Die orrnaal absorpsie na orale toediening is 89 % en gesamentlike toediening met voedsel affekteer nie absorpsie nie. Meloksikam is 99 % proteïen gebonde en het 'n eliminasie halfeeftyd van 15 – 20 ure. Meloksikam is ekstensief gemetaboliseer in die lewer (hoofsaaklik deur oksidasie) en minder as 5 % van die daaglikse dosis word onveranderd uitgeskei in die feses en urine.

INDIKASIES:

FLAMARYX word aangedui vir die simptomatiese behandeling van:
- Rumatoïede artritis.
- Pyrilike osteo-artritis.
- Ankiloserende spondilitis.
- Episodes van akute iskias.

KONTRA-INDIKASIES:
- Hipersensitiwiteit vir **FLAMARYX** of vir enige komponente van die formulering.
- Pasiënte by wie asma aanvalle , urtikariie, neus poliepe of akute rinitus gepresipiteer word deur asetielsalisielsuur/ aspirien of deur ander NSAIMs.
- Aktiewe peptiese ulkus siekte.
- Aktiewe of geskiedenis van herhaalde ulkus/bloeding/perforasies.
- Geskiedenis van gastrointestinale bloeding of perforasie (PUB's), verwant aan vorige NSAIM's.
- Ernstige hepatiese inkorting.
- Ernstige renale inkorting.
- Hartversaking.
- Swangerskap (sien **"SWANGERSKAP EN LAKTASIE"**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
- Kinders onder die ouderdom van 18 jaar – Veiligheid en effektiwiteit is nie vasgestel nie.
- Bejaardes: Bejaardes het 'n verhoogde frekwensie van ongunstige reaksies tot NSAIM's, veral gastrointestinale bloeding en perforasie (PUB's), wat noodlottig kan wees.
- Die risiko van gastrointestinale bloeding of perforasie (PUB's) is hoër met verhoogde dosisse van **FLAMARYX**, by pasiënte met 'n geskiedenis van ulkusse, en bejaardes.
- Wanneer gastrointestinale bloeding of ulserasie voorkom by pasiënte wat **FLAMARYX** ontvang, moet behandeling met **FLAMARYX** gestaak word.
- **FLAMARYX** moet met sorg gegee word aan pasiënte met 'n geskiedenis van gastrointestinale siekte (bv. ulseratiewe kolitis, Crohn se siekte, hiatus breuk, gastroduodenale refluks siekte, angiodisplasie), omdat die kondisie kan vererger.
- Ernstige velreaksies, sommige van hulle noodlotig, insluitende eksfoliatiewe dermatitis, Stevens-Johnson se Sindroom, en toksiese epidermale nekrolise is gerapporteer. **FLAMARYX** moet gestaak word met die eerste verskyning van veluitslag, mukosale letsels, of enige ander teken van hipersensitiwiteit.
- Versigtigheid is nodig by pasiënte met 'n geskiedenis van hipertensie en/of hartversaking omdat vloeistofretensie en edeem gerapporteer is in assosiasie met **FLAMARYX** terapie.
- Kongesteiwee hartversaking verhoog die risiko van renale dekompensasie (sien **"KONTRA-INDIKASIES"**)
- **FLAMARYX** moet met sorg gebruik word by pasiënte met:-
  - Hepatiese inkorting –Verhoog die risiko van renale dekompensasie.
  - Renale inkorting - Verhoog die risiko van renale dekompensasie.

Pasiënte met 'n geskiedenis van gastrointestinale siekte moet baie sorgvuldig gemonitor word terwyl hulle op **FLAMARYX** is en terapie moet gestaak word indien enige ulserasie of bloeding voorkom.
Pasiënte wat gedehidreer is, hepatiese- of nierdisfunksie het, diuretika neem of chirurgie wat gelei het tot hipovolemie ondergaan het, moet nierfunksie sorgvuldig gemonitor word.
Pasiënte wat hartversaking het (sien **"KONTRA-INDIKASIES"**).
In die lig van die produk se inherente potensiaal om vogretensie te veroorsaak, kan hartversaking gepresipiteer word by sommige gekompromiseerde pasiënte.

Effekte op die vermoë om te bestuur en met masjinerie te werk

Pasiënte moet nie masjinerie hanteer of 'n voertuig bestuur indien hulle lomerigheid, dowwe visie of enige ander sentrale senuweestelsel effek ondervind nie.

INTERAKSIES:
- **Asetielsalisielsuur/ Aspirien en ander NSAIM's –** Gebruik van twee of meer NSAIM's gesamentlik kan lei tot 'n verhoging in newe-effekte. Kan tot gevolg hê 'n verhoging in gastriese ulserasie en/of bloeding.
- **Antikoagulante - FLAMARYX** kan die effekte van antikoagulante soos warfarien verbeter, en die risiko van bloedingskomplikasies verhoog.
- **Antiplaatjie middels en selektiewe serotonien heropname inhibeerders (SSRI's) –** verhoogde risiko van gastrointestinale bloeding.
- **Kortikosteroïede –** verhoogde risiko van gastrointestinale ulserasie of bloeding (PUB's).
- **Litium –** Kan tot gevolg hê 'n verhoging in plasmalitiumkonsentrasies. Monitor litiumplasmakonsentrasies sorgvuldig wanneer terapie met **FLAMARYX** begin of onttrek word.
- **Metotreksaat –** Kan tot gevolg hê 'n verhoogde hematologiese toksiiteit as gevolg van metotreksaat toksiiteit.
- **Angiotensien- omskakeling ensiem (AOE) inhibeerders, ARB's en ander antihipertensiewe middels –** Kan tot gevolg hê 'n vermindering in antihipertensiewe effekte en 'n verhoogde risiko van renale versaking.
- **Kardiale glikosiede -** Kan tot gevolg hê 'n verhoging in plasma kardiale glikosiede (bv. digoksien) konsentrasies.
- **Cholestiramien -** Kan tot gevolg hê 'n verminderde terapeutiese effek van **FLAMARYX.**
- **Siklosporien –** Verhoog die risiko van nefrotoksisiteit.
- **Alchohol –** Gelyktydige inname kan die risiko van bloeding verhoog.
- **Diuretika -** Kan tot gevolg hê verhoging in gastriese ulserasie en/of bloeding.
- **Intra-uteriene toestelle –** NSAIM's kan die effektiwiteit van intra-uteriene toestelle verminder.

SWANGERSKAP EN LAKTASIE:

Veiligheid en effektiwiteit by swangerskap en laktasie is nie vasgestel nie. Die gebruik van **FLAMARYX** gedurende die derde trimester van swangerskap word nie aanbeveel nie as gevolg van moontlike ongunstige effekte op die fetus, soos die premature sluiting van die ductus arteriosus, wat kan lei tot volgehoue pulmonêre hipertensie van die pasgeborene. Die aanvang van kraam kan vertraag en die duur daarvan verleng word (sien **"KONTRA-INDIKASIES"**).

DOSIS EN GEBRUIKSAANWYSINGS:

Veiligheid en effektiwiteit by kinders onder die ouderdom van 18 jaar is nie vasgestel nie.
Die tablet moet geneem word met 'n glas water en saam met 'n ete.
Gebruik die laagste effektiewe dosis vir die kortste moontlike tydperk van behandeling.
Die dosis van **FLAMARYX** by pasiënte met endstadium renale siekte op hemodialise moet nie groter as 7,5 mg/dag wees nie. (Geen doseringvermindering is noodsaaklik by pasiënte met ligte tot matige renale inkorting nie).
Volwassenes:
Die maksimum daaglikse dosis van **FLAMARYX** is 15 mg.
Akute iskias: 7,5 mg een keer daaglks. Indien daar geen verbetering is nie, kan die dosis verhoog word tot 15 mg 'n dag.

Ankiloserende spondilitis: 15 mg een keer daagliks.
Osteo-artritis: 7,5 mg een keer daaglks. Verhoog tot 15 mg indien nodig.
Rumatoïede artritis: 15 mg een keer daaglks. Verminder dosis indien moontlik (op voorwaarde dat terapeutiese respons volgehou word).

NEWE EFFEKTE:
Bloed- en die limfatiese stelselafwykings:
Minder dikwels: Anemie, trombositopenie, agranulositose, leukopenie
Die volgende newe effekte is gerapporteer en frekwensies is onbekend: Neutropenie, eosinofilie.

Senuweestelselafwykings:
Minder dikwels: Hoofpyn, duiseligheid, lighoofdigheid, vertigo, lomerigheid, verwarring.
Die volgende newe effekte is gerapporteer en frekwensies is onbekend: Slaaploosheid, nagmerries.

Oogafwykings:
Minder dikwels: Visuele versteurings (soos dowwe visie), konjunktivitis.

Kardiale afwykings:
Minder dikwels: Edeem, palpitasies, verhoogde bloedruk (hipertensie), kardiale versaking.

Respiratories, torakaal en mediastinale afwykings:
Minder dikwels: Bronsgospasma.

Gastrointestinale afwykings:
Die mees algemene ongunstige voorvalle waargeneem is gastroïntestinaal van aard.
Dikwels: Dispepsie, diarree, winderigheid.
Minder dikwels: Peptiese ulkusse, perforasie of gastroïntestinale bloeding, somtyds noodlottig. Perforasie of ulserasie is gewoonlik meer ernstig in bejaardes. Naarheid en braking, hardlywigheid en abdominale pyn, melena, hematemese, ulseratiewe stomatitis, induksie of vereergering van kolitis, gastritis.
Die volgende newe effekte is gerapporteer en frekwensies is onbekend: Verergering van Crohn se siekte.

Hepatobiliêre afwykings:
Minder dikwels: Hepatitis.

Vel- en subkutaneuse weefselafwykings:
Minder dikwels: Pruritis, uitslag, blosing, urtikarie, stomatitis, fotosensitiwiteit, bulleuse reaksie, insluitende veelvuldige eriteem en Stevens-Johnson se sindroom, toksiese epidermale nekrolise.

Renaal en urinêre afwykings:
Minder dikwels: Nefrotiese sindroom, glomerulonefritis, interstisiële nefritis en papillêre nekrose, nierversaking.

Ander:
Minder dikwels: Tinnitis, hipersensitiwiteitsreaksies insluitende anfilakse, angio-edeem en brongospasma (veral indien die pasiënt aspirien-sensitief is en asma en/of neuspoliepe het, moet **FLAMARYX** onmiddellik onttrek word).

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Simptome van oordosering:
(Sien **"NEWE EFFEKTE"**).
Behandeling van oordosering:
Behandeling is simptomaties en ondersteunend aangesien daar geen bekende teenmiddel is nie. Absorpsie moet verminder word deur:
Geaktiveerde houtskool indien pasiënt hom voordoen 1 tot 2 ure na oordosis.
- Cholestiramien.
- Gastriese spoeling indien binne 1 uur na oordosis.

IDENTIFIKASIE:
FLAMARYX 7,5 mg: Ligtegeel, ronde, onbedekte tablette met 'n breeklyn tussen "F" en "1" gebosseleer aan die een kant en gewoon aan die ander kant.
FLAMARYX 15 mg: Ligtegeel, ronde, onbedekte tablette met 'n breeklyn tussen "F" en "2" gebosseleer aan die een kant en gewoon aan die ander kant.

AANBIEDING:
FLAMARYX 7,5 mg:
Tablette is verpak in 250 mikron wit onderuitsigtige PVC bedek met 60 gsm PVdc en gedrukte aluminium foelie met 7 gsm hitteseëllak. 3 Stolpstrokies bevattende 10 tablette elk is verpak in 'n gedrukte karton houer.
Pakgrootte: 30s (3 x 10's).
FLAMARYX 15 mg:
Tablette is verpak in 250 mikron wit onderuitsigtige PVC bedek met 60 gsm PVdc en gedrukte aluminium foelie met 7 gsm hitteseëllak. 3 Stolpstrokies bevattende 10 tablette elk is verpak in 'n gedrukte karton houer.
Pakgrootte: 30s (3 x 10's).

BERGINGSINSTRUKSIES:
Bewaar by of benede 25 °C. Moenie die stolpstroke uit die karton verwyder totdat benodig work vir gebruik.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
SUID AFRIKA:
FLAMARYX 7,5 mg: 42/3.1/0469
FLAMARYX 15 mg: 42/3.1/0470

NAMIBIË:
FLAMARYX 7,5 mg: 10/3.1/0078
FLAMARYX 15 mg: 10/3.1/0079

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
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06 Desember 2021

✂ ♦**DETACH BEFORE DISPENSING** ✂

SUID AFRIKA: S3

NAMIBIË: NS2

FLAMARYX 7,5 mg (tablet)

FLAMARYX 15 mg (tablet)

Meloksikam

Lees die hele brosjure sorgvuldig voordat u begin om FLAMARYX te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **FLAMARYX** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT FLAMARYX BEVAT

Die aktiewe bestanddeel is meloksikam.
FLAMARYX 7,5 mg: Elke onbedekte tablet bevat 7,5 mg meloksikam. Bevat suiker: 23,50 mg laktosemonohidraat.
FLAMARYX 15 mg: Elke onbedekte tablet bevat 15 mg meloksikam. Bevat suiker: 20,00 mg laktosemonohidraat.
Die ander bestanddele is mikrokristallyne sellulose, krospovidoon, laktosemonohidraat, magnesiumstearaat, povidoon, anhidriese kolloïdale silika en natriumsitraat.

2. WAARVOOR FLAMARYX GEBRUIK WORD

FLAMARYX behoort aan 'n groep medisyne wat nie-steroïed anti-inflammatoriese middels (NSAIMs) genoem word. **FLAMARYX** word gebruik om pyn of inflammasie wat deur artritis veroorsaak word, te behandel. Dit kan vir osteoartritis (artritis veroorsaak deur die afbraak van die gewrigsvoering), rumatoïede artritis (artritis veroorsaak deur swelling van die gewrigsvoering) of ankiloserende spondilitis (artritis wat hoofsaaklik die werwelkolom affekteer) gebruik word. **FLAMARYX** word ook gebruik om iskias (lae rugpyn gekombineer met pyn deur die boud en teen een been af) te behandel.

3. VOORDAT U FLAMARYX NEEM

Moenie FLAMARYX neem nie:
- As u aan 'n hongerwone of allergiese reaksie teen meloksikam of enige bestanddeel van die produk gehad het.
- As u al ooit aan asma, neteiroos, neuspoliepe (neusobstruksie weens swelling in die voering van u neus) saam met 'n loopneus wanneer u aspirien of ander NSAIMs gebruik, gely het.
- As u al ooit aan 'n maagsiekte gely het.
- As u al ooit aan gastrointestinale bloeding (bloeding in die maag of ingewande) of gaatjies in die maag of ingewande gely het.
- As u aan hergsleiersiekte ly.
- As u aan hemstige niersiekte ly en nie dialise ondergaan nie.
- As u aan hartversaking ly.
- As u swanger is.

Neem spesiale sorg met FLAMARYX:
- Die veiligheid en effektiwiteit van **FLAMARYX** in pasiënte jonger as 18 jaar oud is nie vasgestel nie.
- As u bejaard is – ouer volwassenes loop 'n groter risiko vir ernstige newe- effekte van die maag of ingewande, insluitende bloeding of perforasie (die vorming van 'n gaatjie). Hierdie kondisies kan fataal wees.
- Die risiko vir ernstige newe effekte van die maag of ingewande, insluitende bloeding of perforasie (die vorming van 'n gaatjie), is ook groter met hoër dosisse **FLAMARYX** en in pasiënte wat voorheen ulkusse gehad het.
- Indien bloeding of ulkusse voorkom terwyl u **FLAMARYX** neem, behoort u met die gebruik daarvan ophou.
- As u al ooit aan enige gastrointestinale siekte bv. ulseratiewe kolitis (n siekte wat inflammasie en sere (ulkusse) in die voering van die dikderm veroorsaak); Crohn se siekte (n tipe inflammatoriese dermsiekte); hiatus hernia (waar 'n gedeelte van die maag deur die diafragma druk) en gastroësofagale refluksiekte (terugvloei van maaginhoud in die slukderm), gely het.
- As u hveluitslag of ander tekens van n allergiese reaksie ondervind, moet u ophou om **FLAMARYX** te neem en u dokter kontak.
- As u ngeskiedenis van hoë bloeddruk en/of hartversaking het.
- As u aan 'n lewersiekte ly.
- As u aan 'n niersiekte ly.
- As u gedehidreerd is, diuretika (watertablette) neem of as u aan hipovolumie ('n afname in bloedvolume) ly wat na chirurgie of 'n lae vloeistofinname kan voorkom.

Die neem van FLAMARYX met voedsel en vloeistof:
- Die tablette behoort met water tydens hmaaltyd geneem te word.
- Die neem van hierdie medisyne saam met alkohol mag die risiko van bloeding verhoog.

Swangerskap en borsvoeding:
- Moenie hierdie medisyne gebruik as u swanger is nie. Hierdie medisyne kan skadelik vir 'n ongebore baba wees. Die neem van **FLAMARYX** gedurende die laaste drie maande van swangerskap kan tot geboortedefekte lei. Stel u dokter in kennis as u swanger is of beplan om gedurende behandeling swanger te raak.
- Die veiligheid van **FLAMARYX** gedurende borsvoeding is nie bevestig nie. Stel u dokter in kennis as u baba borsvoed.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader voordat u hierdie medisyne neem.

Bestuur en die gebruik van masjinerie:
Lomerigheid en onduidelike gesig kan met hierdie medisyne voorkom. Moenie bestuur of masjinerie gebruik voordat u nie weet hoe hierdie medisyne u affekteer nie.

Die neem van ander medisyne saam met FLAMARYX:
Voordat u **FLAMARYX** neem, moet u u dokter in kennis stel as u enige van die volgende medisyne gebruik:
- Aspirien of ander NSAIMs soos diklofenak, indomethasien, ibuprofen
- Medisyne wat bloedklontering voorkom bv. warfarien
- Antiplaatjiemiddels bv. aspirien, klopidogrel, dipridamool
- Selektiewe serotonienheropnaminhibeerders wat in die behandeling van depressie gebruik word
- Kortikosteroïede bv. prednisoon
- Litium
- Metotreksaat
- Angiotensien omskakelingsensiem inhibeerders (AOE) bv. kaptopriel, enalapriel, lisinopriel en ander medisyne wat gebruik word om hoë bloeddruk te behandel
- Cholestiramien – hoofsaaklik gebruik om cholesterolvlakke te verlaag
- Siklosporien
- Enige diuretika (watertablette) – u dokter kan u nierfunksie monitor as u diuretika neem

As u enige van hierdie medisyne neem, kan dit moontlik wees dat u nie **FLAMARYX** kan gebruik nie, of u kan dosisaanpassings kry of u dokter kan u noukeurig vir newe effekte monitor.
- Stel u dokter in kennis as u 'n vrou is wat 'n intrauteriene apparaat (IUA) vir voorbehoeding gebruik. Dit staan gewoonlik as 'n "coil" bekend.

Vertel altyd jou gesondheidsorgdeskundige indien jy enige ander medisyne neem.
(Dit sluit komplementêre of tradisionele medisyne in).

4. HOE OM FLAMARYX TE NEEM
- Neem hierdie medisyne slegs soos deur u dokter voorgeskryf.
- Moenie meer of minder neem of dit meer dikwels as wat u dokter voorgeskryf het, neem nie.
- Die tablette moet met water gedurende hmaaltyd geneem word.
- As u twee tablette moet neem, moet hulle saam as 'nenkele dosis geneem word.

Die normale aanbevole dosisse word hieronder aangedui:
Volwassenes:
- Akute iskias:
  7,5 mg (een tablet) een keer per dag. As daar geen verbetering voorkom nie, kan dit na 15 mg (twee tablette) een keer per dag verhoog word.
- Ankiloserende spondilitis:
  15 mg (twee tablette) een keer per dag.
- Osteoartritis:
  7,5 mg (een tablet) een keer per dag. Dit kan na 15 mg (twee tablette) een keer per dag verhoog word.
- Rumatoïede artritis:
  15 mg (twee tablette) een keer per dag. Dit kan na 7,5 mg (een tablet) een keer per dag verminder word.

Neem altyd **FLAMARYX** presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **FLAMARYX** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

As u te veel FLAMARYX geneem het:
Kry nood mediese hulp as u dink dat u te veel van hierdie medisyne geneem het.

In die geval van oordosis moet u u dokter of apteker raadpleeg. Indien beide nie beskikbaar is nie, moet u die naaste hospitaal of giftebeheersentrum kontak.

As u vergeet het om FLAMARYX te neem:
Neem die oorgeslaande dosis so gou u daarvan onthou. As dit egter byna tyd vir die volgende dosis is, wag en gaan dan met die normale dosisskedule voort.
Moenie die dosis verdubbel om vir die oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE
FLAMARYX kan newe effekte hê.
Kry nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie toon:
- Neteiroos
- Moeite met asemhaling
- Swelling van die gesig, lippe, tong of keel

Raadpleeg onmiddellik u dokter as u enige van hierdie ernstige newe effekte ondervind:
- Swart, bloederige, teeragtige stoelgang, ophoes van bloed, of braaksel wat soos gemaalde koffiebone lyk
- Melkerige of bloederige urien
- Naarheid, maagpyn, verlies aan eetlus, donker urien, kleigekleurde stoelgang, geelsug (geel verkleuring van die vel of oë)
- Urinering minder as gewoonlik of geen urinering nie
- Moeilike of pynlike urinering
- Bleek vel, ongewone moegheid of swakheid
- Abnormale bloeding of kneusing
- Koors, seer keel, en hoofpyn met ernstige blaasvorming, afskilferende en rooi veluitslag
- Veluitslag
- Jeuk
- Hartkloppings (vinnige, ongereelde hartklop)
- Swelling veroorsaak deur vogretensie, insluitende geswelde enkels/bene

Ander moontlike newe effekte sluit die volgende in: Duiseligheid, hoofpyn, lighoofdigheid, lomerigheid, verwardheid, moeite om aan die slaap te raak, nagmerries, diaree, hardlywigheid, bukpyn, inflammasie of seerheid van die maag of kolon, indigestie (maltig), winderigheid (normalige hoeveelheid lug/gas in die maag), naarheid, braking, inflammasie of seerheid van die mond, veluitslag veroorsaak deur blootstelling aan die son, konjunktivitis (rooiheid, pyn, swelling van die oog of die binneste voering van die oogvlies), branderigheid, droë of jeukende oë, uitskeiding of oormatige traanvloei), onduidelike gesig, suising in die ore.
Stel u dokter in kennis as enige van die bogenoemde newe effekte erg of kwellend is, of as hulle nie verdwyn nie.

Nie al die newe effekte wat vir hierdie medisyne aangemeld is, word in hierdie brosjure ingelsluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u hierdie medisyne neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN FLAMARYX

Berg alle medisyne buite die bereik van kinders.

Bewaar teen of benede 25 °C (kamertemperatuur). Moenie die tablette uit die houer verwyder tot voor gebruik nie.

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN FLAMARYX
FLAMARYX 7,5 mg:
Tablette word in 250 mikron wit, onderuitsigtige PVC, bedek met 60 gsm PVdc en gedrukte aluminiumfoelie met 7 gsm hitteseëllak verpak. Elke strokie bevat 10 tablette.
Pakgrootte: 30's (3 X 10's).
FLAMARYX 15 mg:
Tablette word in 250 mikron wit, onderuitsigtige PVC, bedek met 60 gsm PVdc en gedrukte aluminiumfoelie met 7 gsm hitteseëllak verpak. Elke strokie bevat 10 tablette.
Pakgrootte: 30's (3 X 10's).

8. IDENTIFIKASIE VAN FLAMARYX
FLAMARYX 7,5 mg: Liggeel, ronde, onbedekte tablette met 'n breeklyn tussen 'F' en '1' op die eenkant gedruk, en ongedruk op die ander kant.
FLAMARYX 15 mg: Liggeel, ronde, onbedekte tablette met 'n breeklyn tussen 'F' en '2' op die eenkant gedruk, en ongedruk op die ander kant.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER
SUID AFRIKA:
FLAMARYX 7,5 mg: 42/3.1/0469
FLAMARYX 15 mg: 42/3.1/0470

NAMIBIË:
FLAMARYX 7,5 mg: 10/3.1/0078
FLAMARYX 15 mg: 10/3.1/0079

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal Uitbr. 12, 1448
Johannesburg,
Suid Afrika

11. DATUM VAN PUBLIKASIE
Datum van registrasie:
23 Julie 2010
Datum van hersiening:
06 Desember 2021

SCHEDULING STATUS

SOUTH AFRICA: S3

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
FLAMARYX 7,5 mg (tablet)
FLAMARYX 15 mg (tablet)

COMPOSITION:
FLAMARYX 7,5 mg: Each uncoated tablet contains 7,5 mg meloxicam. Contains sugar: 23,50 mg lactose monohydrate.
FLAMARYX 15 mg: Each uncoated tablet contains 15 mg meloxicam. Contains sugar: 20,00 mg lactose monohydrate.

The other ingredients are cellulose microcrystalline, crospovidone, lactose monohydrate, magnesium stearate, povidone, silica colloidal anhydrous and sodium citrate.

PHARMACOLOGICAL CLASSIFICATION:
A3.1 Antirheumatics (anti-inflammatory agents).

PHARMACOLOGICAL ACTION:
Meloxicam, an oxicam (enolic acid) derivative, is a non-steroidal anti-inflammatory compound (NSAID) with analgesic, antipyretic and anti-inflammatory activities. The action of meloxicam is related to inhibition of the enzyme cyclo-oxygenase (COX), resulting in the decreased formation of prostaglandins (mediators of inflammation) and thromboxanes. A selective COX-2 inhibitory (anti-inflammatory effect) *in vitro* in relation to COX-1 has been demonstrated. Inhibition of COX-1 (gastrointestinal, renal and platelet effects) *in vivo* occurs. It is suggested that the extent of inhibition of COX-1 *in vivo* is a function of dose and inter-individual variability of meloxicam concentrations.

Pharmacokinetics:
The extent of absorption after oral administration is 89 % and concomitant administration with food does not affect absorption. Meloxicam is 99 % protein bound and has an elimination half-life of 15- 20 hours. Meloxicam is extensively metabolised in the liver (mainly by oxidation) and less than 5 % of the daily dose is excreted unchanged in the faeces and urine.

INDICATIONS:
FLAMARYX is indicated for the symptomatic treatment of:
- Rheumatoid arthritis.
- Painful osteoarthritis.
- Ankylosing spondylitis.
- Episodes of acute sciatica.

CONTRA-INDICATIONS:
- Hypersensitivity to **FLAMARYX** or to any components of the formulation.
- Patients in who attacks of asthma, urticaria, nasal polyps or acute rhinitis are precipitated by acetylsalicylic acid/ aspirin or by other NSAIDs.
- Active peptic ulcer disease.
- Active or history of recurrent ulcer/haemorrhage/perforations.
- History of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs.
- Severe hepatic impairment.
- Severe renal impairment.
- Heart failure.
- Pregnancy (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
- Children under the age of 18 years - Safety and efficacy have not been established.
- Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.
- The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of **FLAMARYX**, in patients with a history of ulcers, and the elderly.
- When gastrointestinal bleeding or ulceration occurs in patients receiving **FLAMARYX**, treatment with **FLAMARYX** should be stopped.
- **FLAMARYX** should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. **FLAMARYX** should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
- Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with **FLAMARYX** therapy.
- Congestive heart failure increases the risk of renal decompensation (see "**CONTRA-INDICATIONS**").
- **FLAMARYX** should be used with caution in patients with:-
  - Hepatic impairment- Increases risk of renal decompensation.
  - Renal impairment- Increases risk of renal decompensation.

Patients with a history of gastrointestinal disease should be monitored very carefully while on **FLAMARYX** and therapy should be discontinued if any ulceration or bleeding occurs.
Patients who are dehydrated, have hepatic or renal dysfunction, taking diuretics or have undergone surgery leading to hypovolaemia, renal function should be carefully monitored.
Patients who have heart failure (see "**CONTRA-INDICATIONS**").
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Effects on the ability to drive and use machinery
Patients should not operate machinery or drive a vehicle if they experience drowsiness, blurred vision or any other central nervous system effects.

INTERACTIONS:
Acetylsalicylic acid/ Aspirin and other NSAIDS.- Use of two or more NSAIDs concomitantly could result in an increase in side effects. May result in an increase in gastric ulceration and/or bleeding.
Anticoagulants - FLAMARYX may enhance the effects of anti-coagulants such as warfarin, and increase the risk of bleeding complications.
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs) - increased risk of gastrointestinal bleeding.
Corticosteroids - increased risk of gastrointestinal ulceration or bleeding (PUBs).
Lithium - May result in an increase in plasma lithium concentrations. Monitor lithium plasma concentrations carefully when therapy with **FLAMARYX** is initiated or withdrawn.
Methotrexate - May result in increased haematological toxicity due to methotrexate toxicity.
Angiotensin-converting enzyme (ACE) inhibitors, ARBs and other anti-hypertensive agents - May result in a decrease in antihypertensive effects and an increased risk of renal failure.
Cardiac glycosides - May result in an increase in plasma cardiac glycosides (e.g. digoxin) concentrations.
Cholestyramine - May result in a reduced therapeutic effect of **FLAMARYX.**
Ciclosporin - Increases the risk of nephrotoxicity.
Alcohol - Simultaneous intake may increase the risk of bleeding.
Diuretics - May result in renal impairment if the patient is dehydrated (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
Intrauterine devices - NSAIDS may decrease the efficacy of intrauterine devices.

PREGNANCY AND LACTATION:
Safety and efficacy in pregnancy and lactation has not been established.
The use of **FLAMARYX** during the third trimester is not recommended because of possible adverse effects on the foetus, such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. The onset of labour may be delayed and its duration increased (see "**CONTRA-INDICATIONS**").

DOSAGE AND DIRECTIONS FOR USE:
Safety and efficacy in children under the age of 18 years has not been established.
The tablet should be taken with a glass of water and together with a meal.
Use the lowest effective dose for the shortest possible duration of treatment.
The dose of **FLAMARYX** in patients with end stage renal disease on haemodialysis should not be greater than 7,5 mg/day. (No dosage reduction is necessary in patients with mild to moderate renal impairment).

Adults:
The maximum daily dose of **FLAMARYX** is 15 mg.
Acute sciatica: 7,5 mg once daily. If there is no improvement the dose can be increased to 15 mg a day.
Ankylosing spondylitis: 15 mg once daily.
Osteoarthritis: 7,5 mg once daily. Increase to 15 mg if necessary.
Rheumatoid arthritis: 15 mg once daily. Reduce dose if possible (provided therapeutic response is maintained).

SIDE EFFECTS:
Blood and the lymphatic system disorders:
Less frequent: Anaemia, thrombocytopenia, agranulocytosis, leucopoenia.
The following side effects have been reported and frequencies are unknown: Neutropenia, eosinophilia.

Nervous system disorders:
Less frequent: Headache, dizziness, light-headedness, vertigo, drowsiness, confusion.
The following side effects have been reported and frequencies are unknown: Insomnia, nightmares.

Eye disorders:
Less frequent: Visual disturbances (such as blurred vision), conjunctivitis.

Cardiac disorders:
Less frequent: Oedema, palpitations, elevated blood pressure (hypertension), cardiac failure.

Respiratory, thoracic and mediastinal disorders:
Less frequent: Bronchiospasm.

Gastrointestinal disorders:
The most commonly observed adverse events are gastrointestinal in nature.
Frequent: Dyspepsia, diarrhoea, flatulence.
Less frequent: Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Perforation or ulceration is generally more serious in the elderly. Nausea and vomiting, constipation and abdominal pain, melaena, haematemesis, ulcerative stomatitis, induction or exacerbation of colitis, gastritis.
The following side effects have been reported and frequencies are unknown: Exacerbation of Crohn's disease.

Hepato-biliary disorders:
Less frequent: Hepatitis.

Skin and subcutaneous tissue disorders:
Less frequent: Pruritus, rash, flushing, urticaria, stomatitis, photosensitivity, bullous reactions, including erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis.

Renal and urinary disorders:
Less frequent: Nephrotic syndrome, glomerulonephritis, interstitial nephritis and papillary necrosis, renal failure.

Other:
Less frequent: Tinnitus, hypersensitivity reactions including anaphylaxis, angioedema and bronchospasm (especially if patient is aspirin-sensitive and has asthma and/or nasal polyps **FLAMARYX** should be withdrawn immediately).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms of overdosage:
(See "**SIDE EFFECTS**")

Treatment of overdosage:
Treatment is symptomatic and supportive as there is no known antidote. Absorption should be reduced by:
- Activated charcoal if patient presents 1 to 2 hours after overdose
- Cholestyramine
- Gastric lavage if within 1 hour of overdose

IDENTIFICATION:
FLAMARYX 7,5 mg: Light yellow, round, uncoated tablets with score line between 'F' and '1' debossed on one side and plain on the other side.
FLAMARYX 15 mg: Light yellow, round, uncoated tablets with score line between 'F' and '2' debossed on one side and plain on the other side.

PRESENTATION:
FLAMARYX 7,5 mg:
Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer. 3 blisters containing 10 tablets each are packed into a printed cardboard carton.
Pack size: 30's (3 x 10's)
FLAMARYX 15 mg:
Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer. 3 blisters containing 10 tablets each are packed into a printed cardboard carton.
Pack size: 30's (3 x 10's)

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Do not remove the blister from the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
FLAMARYX 7,5 mg: 42/3.1/0469
FLAMARYX 15 mg: 42/3.1/0470

NAMIBIA:
FLAMARYX 7,5 mg: 10/3.1/0078
FLAMARYX 15 mg: 10/3.1/0079

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg.
South Africa

DATE OF PUBLICATION OF PACKAGE INSERT:
Date of registration:
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Date of revision:
06 December 2021

P1500236

✂ **DETACH BEFORE DISPENSING** ✂

SOUTH AFRICA: S3

NAMIBIA: NS2

FLAMARYX 7,5 mg (tablet)
FLAMARYX 15 mg (tablet)
Meloxicam

Read all of this leaflet carefully before you start taking FLAMARYX.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FLAMARYX** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT FLAMARYX CONTAINS
The active substance is meloxicam.
FLAMARYX 7,5 mg: Each uncoated tablet contains 7,5 mg meloxicam. Contains sugar: 23,50 mg lactose monohydrate.
FLAMARYX 15 mg: Each uncoated tablet contains 15 mg meloxicam. Contains sugar: 20,00 mg lactose monohydrate.
The other ingredients are cellulose microcrystalline, crospovidone, lactose monohydrate, magnesium stearate, povidone, silica colloidal anhydrous and sodium citrate.

2. WHAT FLAMARYX IS USED FOR
FLAMARYX belongs to a group of medications called non-steroidal anti-inflammatory drugs (NSAIDs).
FLAMARYX is used to treat pain or inflammation caused by arthritis. It may be used for osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis (arthritis caused by swelling of the lining of the joints), or ankylosing spondylitis (arthritis that mainly affects the spine).
FLAMARYX is also used to treat sciatica (low back pain combined with pain through the buttock and down one leg).

3. BEFORE YOU TAKE FLAMARYX
Do not take FLAMARYX:
- If you have ever had an unusual or allergic reaction to meloxicam or any ingredient of the product.
- If you have ever suffered from asthma, hives, nasal polyps (nasal obstruction due to swellings in the lining in your nose) along with a runny nose when taking aspirin or other NSAIDs.
- If you have or have ever had a ulcer.
- If you have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or holes in the stomach or intestine.
- If you have serious liver disease.
- If you have serious kidney disease and are not undergoing dialysis.
- If you have heart failure.
- If you are pregnant.

Take special care with FLAMARYX:
- The safety and effectiveness of **FLAMARYX** in patients below the age of 18 years has not been determined.
- If you are elderly – older adults have a greater risk of serious side effects on the stomach or intestines, including bleeding or perforation (forming of a hole). These conditions can be fatal.
- The risk of serious side effects on the stomach or intestines, including bleeding or perforation (forming of a hole) is also greater with high doses of **FLAMARYX**, and in patients who have had ulcers.
- If bleeding or ulcers occur while you are taking **FLAMARYX**, you should stop taking **FLAMARYX**.
- If you have ever suffered from any gastrointestinal disease e.g. ulcerative colitis (disease causing inflammation and sores (ulcers) in the lining of the large intestine); Crohn's disease (type of inflammatory bowel disease); hiatus hernia (part of the stomach protrudes through the diaphragm into the chest) and gastro-oesophageal reflux disease (backward flow of stomach contents into the oesophagus).
- If you develop a skin rash or other signs of an allergic reaction, stop taking **FLAMARYX** and contact your doctor.
- If you have a history of high blood pressure and/or heart failure.
- If you have liver disease.
- If you have kidney disease.
- If you are dehydrated, are taking diuretics (water tablets) or if you have hypovolaemia (reduced blood volume) which may occur if you have surgery or low fluid intake.

Taking FLAMARYX with food and drink:
- The tablets should be swallowed with water, during a meal.
- Taking this medicine with alcohol may increase the risk of bleeding.

Pregnancy and Breastfeeding:
- Do not take this medicine if you are pregnant. This medication may be harmful to an unborn baby. Taking **FLAMARYX** during the last 3 months of pregnancy may result in birth defects. Tell your doctor if you are pregnant or plan to become pregnant during treatment.
- The safety of **FLAMARYX** in breastfeeding has not been confirmed. Tell your doctor if you are breastfeeding a baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:
Drowsiness and blurred vision may occur with this medicine. Do not drive or use machinery until you know how this medication affects you.

Taking other medicines with FLAMARYX:
Before taking **FLAMARYX**, tell your doctor if you are using any of the following medicines:
- Aspirin or other NSAIDs such as diclofenac, indomethacin, ibuprofen
- Medicines which prevent blood clotting e.g. warfarin
- Anti-platelet agents e.g. aspirin, clopidogrel, dipyridamole
- Selective serotonin reuptake inhibitors used in the treatment of depression
- Corticosteroids e.g. prednisone
- Lithium
- Methotrexate
- Angiotensin-converting enzyme (ACE) inhibitors e.g. captopril, enalapril, lisinopril and other medicines used to treat high blood pressure
- Cholestyramine – mainly used to lower cholesterol levels
- Ciclosporin
- Any diuretic medicine (water tablets) – your doctor may monitor your kidney function if you are taking diuretics

If you are using any of these medicines, you may not be able to take **FLAMARYX**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.
- Tell your doctor if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil.

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).

4. HOW TO TAKE FLAMARYX
- Take this medication only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor
- The tablets should be swallowed with water, during a meal.
- If you need to take two tablets, they must be taken together as one single dose.

The usual recommended doses are given below:
Adults:
- Acute sciatica:
  7,5 mg (one tablet) once a day. If there is no improvement, this may be increased to 15 mg (two tablets) once a day.
- Ankylosing spondylitis:
  15 mg (two tablets) once a day.
- Osteoarthritis:
  7,5 mg (one tablet) once a day. This may be increased to 15 mg (two tablets) once a day.
- Rheumatoid arthritis:
  15 mg (two tablets) once a day. This may be reduced to 7.5 mg (one tablet) once a day.

Always take **FLAMARYX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **FLAMARYX** is too strong or too weak, talk to your doctor or pharmacist.

If you take more FLAMARYX than you should:
Seek emergency medical attention if you think you have used too much of this medicine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLAMARYX:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS
FLAMARYX can have side effects.
Get emergency medical help at once if you have any of these signs of an allergic reaction:
- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat

Call your doctor immediately if you have any of these serious side effects:
- black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds
- cloudy or bloody urine
- nausea, stomach pain, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes)
- urinating less than usual or not at all
- difficult or painful urination
- pale skin, unusual tiredness or weakness
- unusual bleeding or bruising
- fever, sore throat, and headache with a severe blistering, peeling and red skin rash
- skin rash
- itching
- palpitations (rapid irregular action of heart)
- swelling caused by fluid retention, including swollen ankles/legs

Other possible side effects include: dizziness, headache, lightheadedness, drowsiness, confusion, difficulty in falling asleep, nightmares, diarrhoea, constipation, abdominal pain, inflammation or soreness of the stomach or colon, indigestion (mild), flatulence (excess amount of air/gas in stomach), feeling sick (nausea), being sick (vomiting), inflammation or soreness of the mouth, rashes caused by exposure to sunlight, conjunctivitis (redness, pain, swelling of eye or inner lining of eyelid, burning, dry or itching eyes, discharge, excessive tearing), blurred vision, ringing in your ears.
Tell your doctor if any of the above side effects are severe, bothersome or do not go away.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF FLAMARYX

Store all medicines out of the reach of children.

Store at or below 25 °C (room temperature). Do not remove tablets from the blister until required for use.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF FLAMARYX
FLAMARYX 7,5 mg:
Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.
Pack size: 30s (3 x 10's)
FLAMARYX 15 mg:
Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.
Pack size: 30s (3 x 10's)

8. IDENTIFICATION OF FLAMARYX
FLAMARYX 7,5 mg: Light yellow, round, uncoated tablets with score line between 'F' and '1' debossed on one side and plain on the other side.
FLAMARYX 15 mg: Light yellow, round, uncoated tablets with score line between 'F' and '2' debossed on one side and plain on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER
SOUTH AFRICA:
FLAMARYX 7,5 mg: 42/3.1/0469
FLAMARYX 15 mg: 42/3.1/0470

NAMIBIA:
FLAMARYX 7,5 mg: 10/3.1/0078
FLAMARYX 15 mg: 10/3.1/0079

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg, South Africa

11. DATE OF PUBLICATION
Date of registration:
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Date of revision:
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