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Asunto: **Radicación No.:** **12-48054**
Trámite: **11**
Evento: **379**
Actuación: **519**
Oficio No.: **6370**
Referencia: **Respuesta Oficio de Fondo**

MAURICIO JARAMILLO CAMPUZANO, abogado, identificado con la cédula de ciudadanía No. 80.421.942 de Bogotá y con la tarjeta profesional No. 74.555 del Consejo Superior de la Judicatura, en calidad de apoderado de la solicitante **TARGETED DELIVERY TECHNOLOGIES LIMITED**, doy respuesta al **Oficio No. 6370**, de conformidad con el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, y de acuerdo con los siguientes argumentos:

1. Reivindicaciones:

Las Reivindicaciones 1 y 3 han sido modificadas, eliminando los términos objetados "uno o más" y "cerca de".

Se entiende que las reivindicaciones que ahora se presentan salvan las objeciones del Examinador.

2. Examen de Patentabilidad: Novedad & Nivel Inventivo

Las Reivindicaciones 1 a 5 han sido rechazadas por falta de novedad frente al Documento US 2009/0060990 (D3). Para ello el Examinador afirma que D3 divulga una formulación vesicular que comprende Fosfatidilcolina 6,8% y Polisorbato 80 entre 2,5% y 5,0%, en ausencia de agente activo.

Respetuosamente la Solicitante disiente con el Examinador y, por el contrario, sostiene que lo definido en las reivindicaciones de esta invención es novedoso a la luz de lo divulgado por D3. En efecto, contrariamente a lo sostenido por el Examinador D3 no describe una formulación vesicular que no contenga ingredientes activos. Las formulaciones vesiculares del Ejemplo a que hace referencia el examinador en la página 12, párrafo [0109] de D3, contiene ketoprofeno. El Ketopofeno es una droga anti-inflamatoria no esteroide (NSAID). En efecto, en la definición de la Tabla 2, página 12 de D3, se indica claramente que el Ketoprofeno ("KT") es una droga.

Lo anterior es del conocimiento general de una persona con experiencia en la materia tal como lo evidencia la información disponible en el sitio web Drugs.com de donde se ha obtenido el documento conteniendo información sobre el Ketoprofeno y que se acompaña a la presente respuesta al Oficio 6370. Allí se puede ver claramente que el Ketoprofeno es un anti-inflamatorio no esteroide. Todas las formulaciones vesiculares que comprenden fosfatidilcolina descritas en los ejemplos, y a lo largo de la descripción de D3, contienen Ketoprofeno. Por lo tanto, no se describen en D3 formulaciones vesiculares que comprendan fosfatidilcolina *"en ausencia de un agente farmacéuticamente activo"*, tal como se define en la Reivindicación 1 de la presente solicitud.

El Ejemplo 3 de la presente solicitud muestra, en las Figuras 20 a 23, los resultados de ensayos clínicos utilizando la formulación vesicular de D3 (es decir la formulación vesicular conteniendo Ketoprofeno, denominada IDEA-070) para el tratamiento de desórdenes de dermatosis inflamatoria. Una formulación vesicular de acuerdo con la presente invención fue utilizada como placebo de control en este Ejemplo. Las composiciones de las dos formulaciones son las mismas excepto por la ausencia del Ketoprofeno en el placebo de control. Resulta claro de este Ejemplo que el placebo de control,

sorprendentemente e inesperadamente, tienen la misma capacidad terapéutica que las vesículas que contienen Ketoprofeno para tratar los desórdenes de dermatosis inflamatoria. Claramente, el uso de una formulación sin Ketoprofeno para aliviar los síntomas es muy beneficioso dado que los pacientes con este tipo de enfermedades pueden ser tratados sin experimentar los usuales efectos secundarios que están asociados al agente farmacéuticamente activo tal como los anti-inflamatorios no esteroides. Por supuesto, en estas condiciones resulta mucho más económico el tratamiento de estos pacientes.

Por lo tanto, analizando el contenido de la Reivindicación 1 que ahora se presenta y lo divulgado en D3 se puede concluir que las formulaciones reivindicadas en la presente solicitud son nuevas porque no contienen un agente farmacéuticamente activo como sucede en aquellas formulaciones divulgadas. Por otra parte, también puede concluirse que las formulaciones aquí reivindicadas presentan nivel inventivo porque los resultados obtenidos con las mismas, sin agente farmacéuticamente activo, en los pacientes tratados son los mismos que aquellos obtenidos con las formulaciones que sí contienen un agente activo para tratar las enfermedades en cuestión. Esto, indudablemente, es un resultado sorprendente e inesperado para una persona experta en el arte por lo tanto, lo propuesto por la invención no debería resultarle obvio. Nada en D3 le indica a esta persona que puede utilizarse la formulación de D3 sin el agente farmacéuticamente activo.

Por todo lo argumentado y en virtud de las nuevas reivindicaciones ajustadas para salvar las objeciones formuladas en el Oficio que aquí se responde se le solicita al examinador la reconsideración de sus objeciones y rechazo.

Notificaciones

Recibiré notificaciones en la secretaría de su Despacho; en mis oficinas de abogado ubicadas en la Calle 67 No. 7 - 35, oficina 1204, teléfono 3192900, fax 3210295, Bogotá D.C., Colombia, o; al correo electrónico apenaranda@gpzlegal.com.

Atentamente,



MAURICIO JARAMILLO C.
C.C. 80.421.942 de Bogotá
T.P. 74.555 del C.S.Jra.

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Adjunto: Lo anunciado

- Nuevo capítulo reivindicatorio.
- Información sobre Ketoprofen (obtenido del sitio Drugs.com)

REIVINDICACIONES

1. Una formulación vesicular que comprende un fosfolípido y un surfactante no iónico seleccionados de entre el grupo compuesto por: Sorbitanes de polioxietileno, 5 estearatos de polihidroxietileno o lauriléteres de polihidroxietileno, en ausencia de un agente farmacéuticamente activo, y que se caracteriza porque la formulación contiene 2,0-10,0% por peso de fosfolípidos y que se caracteriza 10 porque la formulación contiene 0,2-5,0% por peso de surfactante.

2. la formulación vesicular de la reivindicación 1, que se caracteriza porque la formulación es una crema, 15 loción, pomada, gel, solución, aerosol, laca o solución formadora de película.

3. Una formulación vesicular como la de la reivindicación 1 o la reivindicación 2, que se caracteriza 20 porque la proporción de fosfolípido a surfactante es de 1:3 a 30:1.

4. Una formulación vesicular, como la de cualquiera de las reivindicaciones 1 a 3, que se caracteriza porque el 25 fosfolípido es fosfatidilcolina.

5. Una formulación vesicular, como la de cualquiera de las reivindicaciones 1 a 4, que se caracteriza porque el surfactante es polisorbato 80 (Tween 80).



The following information is not a substitute for the knowledge and judgement of a healthcare professional. It should not be construed to indicate that use of the drug is safe, appropriate, or effective for you. Always consult with your doctor, nurse, or pharmacist before taking medication.

ketoprofen

Generic Name: ketoprofen (kee toe PROE fen)

Brand Name: *Actron, Orudis KT, Orudis, Oruvall*

What is ketoprofen?

Ketoprofen is in a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). Ketoprofen works by reducing hormones that cause inflammation and pain in the body.

Ketoprofen is used to treat pain or inflammation caused by arthritis. It is also used to treat menstrual pain.

Ketoprofen may also be used for other purposes not listed in this medication guide.

What is the most important information I should know about ketoprofen?

This medicine can increase your risk of life-threatening heart or circulation problems, including heart attack or stroke. Do not use this medicine just before or after having heart bypass surgery (also called coronary artery bypass graft, or CABG).

Seek emergency medical help if you have symptoms of heart or circulation problems, such as chest pain, weakness, shortness of breath, slurred speech, or problems with vision or balance.

This medicine can also increase your risk of serious effects on the stomach or intestines, including bleeding or perforation (forming of a hole). These conditions can be fatal and gastrointestinal effects can occur without warning at any time while you are taking ketoprofen. Older adults may have an even greater risk of these serious gastrointestinal side effects.

Call your doctor at once if you have symptoms of bleeding in your stomach or intestines. This includes black, bloody, or tarry stools, or coughing up blood or vomit that looks like coffee grounds.

What should I discuss with my healthcare provider before taking ketoprofen?

Taking an NSAID can increase your risk of life-threatening heart or circulation problems, including heart attack or stroke. This risk will increase the longer you use an NSAID. Do not use this medicine just before or after having heart bypass surgery (also called coronary artery bypass graft, or CABG).

NSAIDs can also increase your risk of serious effects on the stomach or intestines, including bleeding or perforation (forming of a hole). These conditions can be fatal and gastrointestinal effects can occur without warning at any time while you are taking an NSAID. Older adults may have an even greater risk of these serious gastrointestinal side effects.

You should not use this medication if you are allergic to ketoprofen, or to aspirin or other NSAIDs.

Before taking ketoprofen, tell your doctor if you are allergic to any drugs, or if you have:

- a history of heart attack, stroke, or blood clot;
- heart disease, congestive heart failure, high blood pressure;
- a history of stomach ulcers or bleeding, bowel problems, diverticulosis;
- liver or kidney disease;
- asthma;
- polyps in your nose; or
- if you smoke.

If you have any of these conditions, you may need a dose adjustment or special tests to safely take this medication.

FDA pregnancy category C. It is not known whether ketoprofen is harmful to an unborn baby. Before taking this medication, tell your doctor if you are pregnant or plan to become pregnant during treatment.

It is not known whether ketoprofen passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

Do not give this medicine to a child without the advice of a doctor.

How should I take ketoprofen?

Take this medication exactly as directed on the label, or as it has been prescribed by your doctor. Do not use the medication in larger amounts, or use it for longer than recommended. Ketoprofen should not be used to treat minor aches and pains.

If you take ketoprofen for a long period of time, your doctor may want to check you on a regular basis to make sure this medication is not causing harmful effects. Do not miss any scheduled visits to your doctor.

Store ketoprofen at room temperature, away from moisture, heat, and light.

What happens if I miss a dose?

Since ketoprofen is sometimes taken as needed, you may not be on a dosing schedule. If you are taking the medication regularly, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention if you think you have used too much of this medicine. Overdose symptoms may include nausea, vomiting, dizziness, drowsiness, black or bloody stools, coughing up blood, urinating less than usual or not at all, shallow breathing, fainting, seizure (convulsion), or coma.

What should I avoid while taking ketoprofen?

Do not use any other over-the-counter cold, allergy, or pain medication without first asking your doctor or pharmacist. Many medicines available over the counter contain medicines similar to ketoprofen (such as

aspirin, ibuprofen, or naproxen). If you take certain products together you may accidentally take too much of this type of medication. Read the label of any other medicine you are using to see if it contains aspirin, ibuprofen, or naproxen.

Do not drink alcohol while taking ketoprofen. Alcohol can increase the risk of stomach bleeding.

Ketoprofen side effects

Get emergency medical help if you have any of these **signs of an allergic reaction**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop taking ketoprofen and seek medical attention or call your doctor at once if you have any of these serious side effects:

- chest pain, weakness, shortness of breath, slurred speech, problems with vision or balance;
- black, bloody, or tarry stools, coughing up blood or vomit that looks like coffee grounds;
- confusion, tremors or shaking;
- urinating less than usual or not at all;
- nausea, stomach pain, low fever, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- fever, sore throat, and headache with a severe blistering, peeling, and red skin rash;
- bruising, severe tingling, numbness, pain, muscle weakness.

Less serious side effects may include:

- upset stomach, mild heartburn or stomach pain, diarrhea, constipation; bloating, gas;
- dizziness, headache, nervousness;
- skin itching or rash;
- dry mouth;
- increased sweating, runny nose;
- blurred vision; or
- ringing in your ears.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Ketoprofen dosing information

Usual Adult Dose for Osteoarthritis:

Ketoprofen: 75 mg orally 3 times a day or 50 mg orally 4 times a day.
The recommended maximum is 300 mg/day.

Ketoprofen Extended-release: 200 mg orally once daily.

Usual Adult Dose for Rheumatoid Arthritis:

Ketoprofen: 75 mg orally 3 times a day or 50 mg orally 4 times a day.
The recommended maximum is 300 mg/day.

Ketoprofen Extended-release: 200 mg orally once daily.

Usual Adult Dose for Acute Gout:

Ketoprofen: 100 mg orally one time, followed by 50 mg every 6 hours until the acute gouty attack has resolved, usually 2 to 3 days.

Usual Adult Dose for Pain:

Ketoprofen: 25 to 50 mg orally every 6 to 8 hours. Dose may be increased up to a maximum of 75 mg.

Usual Adult Dose for Fever:

Ketoprofen: 12.5 mg orally every 4 to 6 hours. An additional dose may be given if the fever does not improve within 1 hour.

The maximum daily dose should not exceed 75 mg.

Usual Adult Dose for Dysmenorrhea:

Ketoprofen: 25 to 50 mg orally every 6 to 8 hours as needed for pain relief. The dose should be titrated to patient response and should not exceed 300 mg/24 hours.

What other drugs will affect ketoprofen?

Tell your doctor if you are taking an antidepressant such as citalopram (Celexa), duloxetine (Cymbalta), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem, Symbyax), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), or venlafaxine (Effexor). Taking any of these drugs with ketoprofen may cause you to bruise or bleed easily.

Before taking ketoprofen, tell your doctor if you are taking any of the following drugs:

- cyclosporine (Gengraf, Neoral, Sandimmune);
- lithium (Eskalith, Lithobid);
- methotrexate (Rheumatrex, Trexall);
- probenecid (Benemid);
- a blood thinner such as warfarin (Coumadin), or an anti-platelet medication such as clopidogrel (Plavix), dipyridamole (Persantine), ticlopidine (Ticlid), and others;
- steroids (prednisone and others);
- aspirin, or other NSAIDs such as diclofenac (Voltaren), etodolac (Lodine), fenoprofen (Nalfon), flurbiprofen (Ansaid), ibuprofen (Advil, Motrin), indomethacin (Indocin), ketorolac (Toradol), mefenamic acid (Ponstel), meloxicam (Mobic), nabumetone (Relafen), naproxen (Aleve, Naprosyn), piroxicam (Feldene), and others.

This list is not complete and there may be other drugs that can interact with ketoprofen. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

Where can I get more information?

- Your pharmacist can provide more information about ketoprofen.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines

with others, and use this medication only for the indication prescribed.

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