An open-label, exploratory, randomised, three-period, six-sequence single dose crossover study comparing the safety, tolerability and pharmacokinetic profile of a new and marketed flurbiprofen (8.75 mg) spray in healthy male/female subjects under fasting conditions.

Published: 13-09-2018
Last updated: 12-04-2024

The objectives of this exploratory study are: * To evaluate the safety and local tolerability of the new flurbiprofen 8.75 mg spray. * To compare the pharmacokinetic profile of the new flurbiprofen 8.75 mg spray to marketed flurbiprofen 8.75 mg…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48429

Source
ToetsingOnline

Brief title
Safety, tolerability and PK study of a new flurbiprofen 8.75 mg spray

Condition

- Other condition

Synonym
Sore throat

Health condition

Ear, nose and throat diseases

Research involving
Human

Sponsors and support

Primary sponsor: Reckitt Benckiser Healthcare (UK) Limited
Source(s) of monetary or material Support: Reckitt Benckiser

Intervention

Keyword: Flurbiprofen, Pharmacokinetic, Safety, Tolerability

Outcome measures

Primary outcome

Safety Endpoints: The safety and local tolerability will be determined by:

Changes to the oral mucosa as graded using WHO oral mucositis guidelines.

Subject responses to the HSE irritancy questionnaire for each product over time

Secondary outcome

Secondary Endpoints: The following key PK, and other derived parameters for the

test (A and B) and reference Investigational Medicinal Products (IMPs) will be

assessed:

Cmax - the maximum observed plasma concentration.

AUC0-t - the area under plasma concentration curve from administration to last

quantifiable concentration at time t.

Tmax - the time to maximum observed concentration.

AUC0-inf - the AUC extrapolated to infinity.

T1/2: elimination half life

Study description

Background summary

Reckitt Benckiser (RB) have developed a new flurbiprofen 8.75 mg spray which aims to provide greater perception of efficacy in the sore throat area.

An exploratory clinical study is required to establish the safety and tolerability profile of the new flurbiprofen 8.75 mg spray. This clinical study will include two new flurbiprofen 8.75 mg sprays which have identical characteristics but differ in flavour, and the marketed flurbiprofen 8.75 mg spray as a reference product.

In addition to establishing the safety and tolerability profile of the new flurbiprofen 8.75 mg spray, the clinical study will also include an analysis of the pharmacokinetic profile of flurbiprofen and an organoleptic assessment to establish a preferred flavour.

Study objective

The objectives of this exploratory study are:
* To evaluate the safety and local tolerability of the new flurbiprofen 8.75 mg spray.
* To compare the pharmacokinetic profile of the new flurbiprofen 8.75 mg spray to marketed flurbiprofen 8.75 mg spray.
* To identify flavour preference of the new flurbiprofen 8.75 mg spray.

Study design

This is an open label, exploratory, randomised, three-period, six-sequence single dose crossover study.

Intervention

Flurbiprofen 8.75 mg (Mint and Cherry Flavour) spray
Flurbiprofen 8.75 mg (Lemongrass and Ginger) spray
Flurbiprofen 8.75 mg (Mint and Cherry) spray

Study burden and risks

The dosage levels of the study drug are based on a previous clinical trial conducted by the sponsor. The risk to health at the chosen
dose is limited, but the patients may experience any of the side effects in the ICF or symptoms that have not been reported before.
Volunteer health is closely monitored during the study to minimize these risks.

If the volunteers experience side effects, the investigator will treat them where necessary. If new information is available on the safety of the study medication, the volunteers are informed as soon as possible. The blood collection procedure is not dangerous.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Only subjects to whom all of the following conditions apply will be included:
1. Subject has provided written informed consent.
2. Subject is male or female and aged: * 18 years * 55 years.
3. Subjects with a Body Mass Index (BMI) of * 18.5 and * 30kg/m2.
4. Subject is healthy with no clinically significant abnormal findings as determined by medical history, physical examination, vital signs, laboratory tests and echocardiogram (ECG) at

screening.
5. Subjects with normal oral mucosa (score of 0 on the WHO Oral Mucositis Guideline).
6. Female subjects of child bearing potential willing to use a highly effective method of contraception throughout the study.
OR Female subjects who are post-menopausal or permanently sterilised.
7. Subjects who are willing to abstain from food and drinks that contains either caffeine, xanthine, grapefruit (including marmalade and juice) and poppy seeds for 48 hours prior to the first drug administration until the end of the last treatment period.
8. Subjects who are willing to abstain from strenuous exercise for 72 hours prior to the first drug administration until the end of the
last treatment period.
9. Subject is willing to comply with all study procedures and is available for the duration of the study.

Exclusion criteria

Subjects to whom any of the following conditions apply must be excluded:
1. Subject has a current or previous clinically significant medical history, as determined by the Investigator, including, but not limited to cardiovascular, hepatic, renal, respiratory, gastro-intestinal, neurological, metabolic, ear, nose and throat (ENT), dental and psychiatric disorders.
2. Subject has any condition that may currently interfere with the absorption, distribution, metabolism or excretion of drugs.
3. Subject has any taste disorder.
4. Subject has a known history of previous allergy, anaphylactic reactions or intolerance related to treatment with flurbiprofen, ibuprofen or other NSAIDs, codeine or the excipients of the test or reference IMPs.
5. Subject is a current smoker (including e-cigarettes) or ex-smoker who has smoked or used nicotine-containing products within 3 years of screening.
6. Subject has a history of drug or alcohol abuse according to the DSM-IV classification or a positive test for drugs of abuse and/or alcohol at screening.
7. Subject has used prescription or non-prescription drugs, including NSAIDs, vitamins, herbal and dietary supplements (with the exception of the continued use of HRT and contraceptives) in the 14 days (or 5 half-lives of the drug, whichever is longer) before first drug administration.
8. Subject has donated 450 mL (or more) blood, including blood products, or has significant loss of blood in the 90 days prior to screening or at any time during the study, except as required by this protocol.
9. Subject has known human immunodeficiency virus (HIV) positive status, or a positive viral serology screen (Hepatitis B surface antigen (HBsAg), Hepatitis C antibody, HIV tests).
10. Female subject who is pregnant as confirmed by a positive pregnancy test or is lactating.
11. Subject has received an investigational product, or participation in another trial involving a marketed or investigational drug in the 30 days prior to first drug administration.
12. Subject who is an employee at the Clinical Unit or is a partner or first degree relative of the Investigator.

13. Subject fails to satisfy the investigator of fitness to participate for any other reason.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2019
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Flurbiprofen 8.75 mg (Lemongrass and Ginger) spray
Generic name:	N.A.
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-09-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	07-12-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-003175-36-NL
CCMO	NL67219.056.18

Study results

Results posted: 04-05-2020

First publication

09-03-2020