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To gain further information about the safety of EPs® 7630 film-coated tablets (Kaloba 20 mg Filmtabletten) in adult subjects (greater than or equal to 18 years old) suffering from common cold symptoms

Submission date 02/12/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/01/2011	**Overall study status** Completed	
Last Edited 18/05/2021	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Protocol serial number
701004.01.012

Study information

Scientific Title
EPs® 7630 film-coated tablets in subjects (greater than or equal to 18 years old) suffering from common cold: a prospective, multicentre, single-arm, open-label, phase IV clinical post-marketing safety study

Study objectives
The objective of the present post-marketing study is to gain further information about the safety and treatment outcome with EPs® 7630 film-coated tablets (Kaloba 20 mg Filmtabletten) in adult subjects (greater than or equal to 18 years old) suffering from common cold.

Please note that as of 18/09/2012, the anticipated end date of this trial has been updated from 31/12/2011 to 31/12/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommissionder Medizinischen Universität Graz approved on the 16th December 2010 (ref: 23-076e x 10/11)

Study design
Prospective multicentre single-arm open-label phase IV safety study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Common cold

Interventions
One EPs® 7630 film-coated tablet (Kaloba 20 mg Filmtabletten) three times a day for a period of 10 consecutive days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
EPs® 7630

Primary outcome(s)
1. Adverse events surveillance
2. Treatment outcome according to the Integrative Medicine Outcomes Scale (IMOS) as assessed by the investigator (day 3, 5 and 10) and the subject (visit 2 and 3), respectively
3. Change in individual common cold symptoms (CCS) and total score of CCS from baseline (day

1) to visit 2 and visit 3, respectively, as assessed by the investigator
4. Change in further common cold relevant complaints from baseline (day 1) to visit 2 and visit 3, respectively, as assessed by the investigator
5. Change in total score of common cold symptoms and further common cold relevant complaints from baseline (day 1) to visit 2 and visit 3, respectively, as assessed by the investigator
6. Change in common cold symptoms (CCS) as rated by the subject in the subject's diary
7. Number of subjects who are 'not sick' or 'very mildly sick' as rated daily by the subject in the subject's diary when answering the question 'how sick do you feel today?'
8. Duration of subject's off work or inability to attend school/college (checked daily)
9. Need for subject's treatment with antibiotics during the study period according to the medical decision of the investigator
10. Use of paracetamol tablets from baseline (day 1) to individual study end
11. Satisfaction of the subject with the treatment according to the Integrative Medicine Patient Satisfaction Scale (IMPSS) as assessed by the subject in the subject's diary at day 10

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Male and female subjects aged greater than or equal to 18 years old
2. Written informed consent
3. Subject suffers from common cold
4. Presence of at least two common cold symptoms
5. First common cold symptom started less than or equal to 72 hours prior to inclusion into the study
6. Subject with willingness and ability to comply with all procedures of the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Obstructive anatomic lesions in the nasopharynx such as nasal polyps, or severe septal deviations
2. Previous surgery (within the last 12 months prior to inclusion into the study) or need for surgery of the nose or paranasal sinuses including sinus puncture
3. Presence of any acute respiratory tract disease (e.g. tonsillitis, sinusitis, otitis media, bronchitis, pneumonia) other than common cold
4. Subjects with known or suspected allergic rhinitis
5. Subjects with other explanations of sore throat (e.g. tonsillo-pharyngitis, drugs, aphthous ulcers, candida, etc.)
6. Subjects with previous rheumatic fever within the last 12 months prior to inclusion into the trial
7. Subjects with several previous complications of tonsillitis (quinsy)
8. Chronic lung diseases (e.g. chronic bronchitis, COPD, bronchial asthma, cystic fibrosis, active pulmonary tuberculosis, lung cancer)
9. History of recurrent tonsillitis or otitis media of greater than 3 episodes during the last 12 months prior to enrolment into the study
10. History of recurrent bronchitis of greater than 6 episodes during the past 12 months prior to enrolment into the study
11. History of recurrent sinusitis of greater than 3 episodes during the past 12 months prior to enrolment into the trial or chronic sinusitis (symptoms lasting for greater than 1 month)
12. Previous (within the last 6 weeks prior to inclusion into the clinical trial) or concomitant treatment with anti-coagulants
13. Concomitant common cold medications that might impair the interpretation of trial results
14. Known or suspected hypersensitivity to the investigational drug
15. Severe cardiovascular disease, unstable diabetes mellitus, or immunosuppression
16. History of renal or hepatic dysfunction (serum creatinine, serum aspartate aminotransferase [AST], alanine aminotransferase [ALT] or alkaline phosphatase of greater than 3 times above the upper limit of normal values) at any time during the past 12 months prior to enrolment into the trial
17. Known alcohol or drug abuse
18. Subjects with tendency to bleed, especially nose or gingival bleeding
19. Known gastrointestinal disorders (e.g. gastritis, duodenitis, colitis, gastric ulcer, partial or total gastrectomy, enterectomy, inflammatory bowel disease, coeliac disease, symptomatic lactose intolerance, other disorders associated with chronic diarrhoea)
20. Females of child-bearing potential without adequate contraception
21. Pregnancy or lactation
22. Subjects participating in another clinical trial at the same time or have taken part in a clinical trial during the last 4 weeks before inclusion into this study
23. Irresponsible subjects or those unable to understand nature, meaning and consequences of the trial

Date of first enrolment
10/01/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment

Austria

Germany

Study participating centre
Dr. Willmar Schwabe GmbH & Co. KG
Karlsruhe
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Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/04/2021	18/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes