

Swallowing medicines

**Gloup® or Apple Compote?
Vanilla yoghurt?
Crushing tablets/
Opening capsules?**

**Information for
pharmacists**



Using Gloup® for the first time? Try it first without tablets!

The taste and structure of Gloup® may take a little getting used to.



The first universal gel that has been especially developed for swallowing solid medicines

Scientific research into the 'gel that makes solid medicines easier to swallow'.

The idea for a 'gel that makes solid medicines easier to swallow' came to a nurse in 2008 as a result of experience gained in the profession. Following on from the initial registration of the concept with the INPI (Institut Nationale de la Propriété Industrielle), the idea was further developed by the Ecole de Biologie Industrielle (E.B.I.) in Cergy-Pontoise, under the leadership of Prof. Dr. Anne-Marie Pensé-Lhéritier, professor of formulation development, and Prof. Dr. Christine Mielcarek, professor of microbiology.

The aim of this research was: 'to develop a product which makes solid medicines easier to swallow' and which fulfils the following criteria: a gel-like substance with a good texture in the mouth (sufficiently thick and slippery), that does not stick to the mucous membrane in the mouth and throat cavity and is easy to swallow. The product must also have a pleasantly sweet flavour and be capable of camouflaging the taste of medicines; it must have an appealing colour and be suitable for both young and old. An additional objective was that all of the ingredients should be 'food grade' and, where possible, also natural.

The results of the research by the E.B.I. were set out in the 'Rapport de Faisabilité PTR 10-200 van 20 November 2011' PTR 10-200 of 20 November 2011'.

These results led to applications for and the allocation of two patents in France and the Netherlands (patent application 1060885 of 21 December 2010 and patent application 1039241 of 14 December 2011 respectively, followed by patents granted on 26 January 2013 and 11 September 2012 respectively).

Gloup® is the worldwide registered brand name for the gel that was the end-result of the research, thus achieving the objectives: a simple product for the user created on a thorough scientific basis.
Judge for yourself!

Gloup® is so simple, why did nobody think about it before?



References:

• Rapport de Faisabilité PTR 10-200, Ecole de Biologie Industrielle – Cergy Pontoise, 24 March 2011; • NL Agency, Ministry of Economic Affairs, Patent 1039241, approved on 11 September 2012; • Gloup, evaluation of toxicity, from approval file Medical Aids: Category I, April 2013.

In line with the targets, the scientific research concentrated on the following areas:

I. Thickeners

Research was conducted into four thickeners and, as far as possible, their respective combinations. The following criteria were investigated:

- Viscosity
- Slipperiness in the mouth cavity
- Concentration
- Rheology of the various gels

Conclusion/result: on the basis of the evaluated test results, it was concluded that the research should focus on one specific carrageen in various concentrations.

II. Formulation

Research was conducted into which formulations best fulfilled the objectives set, on the basis of the thickener selected. The following criteria were prioritised:

- Choice of colorant
- Choice of flavouring
- Choice of preservative (with bacteriological research according to the European Pharmacopoeia guidelines).

Conclusion/result: colorant, flavouring and aspartame levels were defined. The first two, on a natural basis. It was established that the preservative potassium sorbate was effective against the five microbiological strains in the challenge tests.

III. Stability

Research into shelf-life and storage conditions and the capacity to retain flavour, aroma, colour, texture and effectiveness in relation to quality characteristics pH and viscosity.

Conclusion/result: The chosen end-product was capable of retaining aroma, colour, texture and effectiveness and not contain any bacteriological or fungal contamination at the end of the test period.

IV. Taste and feeling in the mouth

Establishing the extent to which the selected gel fulfils the following taste and mouth-feeling criteria:

- Stickiness
- Hardness
- Degradability
- Capacity to melt
- Capacity to slide

Conclusion/result: The selected product hardly sticks at all in the mouth/throat cavity; it is not hard, is very fluid and extremely slippery.

V. Validation as a swallowing gel

A trial, using healthy volunteers who had no problems swallowing, established (according to protocols) how the intake time of (placebo) medicines differed between two selected gels (different concentrations of thickener) and water. Research was also conducted into the value of the product as a swallowing gel for medicines.

Conclusion/result: After the trial, >40% of users (eight of the nineteen), without swallowing problems, indicated that they preferred the swallowing gel over water in terms of taking medicines. The average intake time with water was 6.11 seconds; with the swallowing gel it was 7.08 seconds. Two of the trial participants found that the intake time reduced from 13 or 27 seconds with water, to 5 or 4 seconds with the swallowing gel. Agreements for scientific follow-up research have been made with the UMC Groningen.

What do these results mean in practice?

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- Gloup® is a recognised Medical Aid, Category I.
- Gloup® is a thick, slippery gel that makes medicines easier to swallow.
- Gloup® has a pleasant, fresh cherry flavour that camouflages the taste of medicines.
- Gloup® is made up of >99% natural ingredients, all with 'food grade' status.
- Gloup® is capable of effectively moistening the mouth and throat cavity without sticking to the roof of the mouth.
- Gloup® biodegrades into inactive elements in the stomach as a result of the acidic environment.
- Gloup® is protected against microbiological contamination; an open tube kept at a temperature of between 2 and 25°C will not pose any threat for a minimum of two months.
- Gloup® does not contain sugar or gelatine and is free from allergens.
- Gloup® can be used in most circumstances and has no known interactions with existing medicines; it is suitable for almost all medicine users (from the age of 2).

Gloup® or Apple compote?



Arzneimittel werden noch regelmäßig mit Apfelsmus heruntergeschluckt. Ist das empfehlenswert?

Properties	Gloup®	Apple compote*	Consequences of use with apple compote
Medical Aid?	Class I	No	No advice possible
Thick, lubricant?	Yes	No, varies	Pills may get 'stuck'
Camouflages the taste of pills?	Yes	Virtually	...
Natural ingredients?	Yes, >99%	Unknown	Composition not universally established
Visco elasticity?	Yes	No	No pill encapsulation, which causes pill to remain 'stuck' in the throat
'Peeling' effect?	No	Yes	Potentially taints protective layer of pill or capsule
Interactions?	No known interactions, universal gel	Potentially unsuitable universally, due to relatively low pH of malic acid and ascorbic acid	May affect a range of medication. Most well known: HIV medication, antimycotics
Sugar?	<0.1 grams/100ml	Minimum 18 grams/100ml	Not suitable for diabetics
Take on an empty stomach?	Yes	No	Disrupts empty stomach
Gluten?	No	No	...
Allergens?	No	Yes, added fruit types also create unexpected reactions sometimes	Apple contains type IgE allergens, which may cause OAS (Oral Allergy Syndrome)
Calories?	7 kcal/100ml	80 kcal/100ml	In addition to more calories, more apple compote is also necessary
Microbiological protection?	Yes, 2 months from 2 - 25°C	No, must be kept refrigerated after opening	Max. 2 days shelf life, spoils quickly if not refrigerated

* Apple compote means ready-made apple compote, as defined in the Food and Drugs Act in force. Home-made apple compote may contain other ingredients.

What are the implications for your patient?

By improving compliance, Gloup® contributes to more effective pharmacotherapy. It is the only Medical Aid that is suitable for taking all permanent medication. Gloup® is only available from pharmacists.

Gloup® or Vanilla yoghurt?



Arzneimittel wurden und werden oft mit Milchprodukten geschluckt, z.B. mit Pudding. Ist das empfehlenswert?

Property	Gloup®	Vanilla yoghurt	Consequences for vanilla yoghurt user
Medical aid	Category I	No	No advice available
Thick, slippery	Yes	Thick, not slippery	Tablets can 'hang around'
Camouflages taste of tablets	Yes	More or less	...
Natural ingredients	>99%	<99%	...
Visco elasticity	Yes	No	Does not coat outside of tablet
'Peeling' effect	None	Probably	May damage protective layer on tablet or capsule
Interactions	None known, universal gel	Tetracyclines, quinolones, bisphosphonates	Not universally suitable and composition varies (vanilla, chocolate, caramel)
Sugar	<0.1 gram/100 ml	>8 gram per 100 ml	Not suitable for diabetics
Intake on empty stomach	Yes	No	Disrupts empty stomach
Gluten	No	Can vary from one to another	Not excluded, composition varies
Allergens	No	Cow's milk/lactose	Allergy
Emulsifier	No	Yes	Potential effect on absorption
Calories	9	80-100kcal/100ml	More vanilla yoghurt needed
Microbiological protection	Yes, 2 months between 2 and 18°C	None, max. 3-4 days in fridge after opening	Short shelf-life, risk of bacterial contamination, not very 'portable'

* Apple compote means ready-made apple compote, as defined in the Food and Drugs Act in force. Home-made apple compote may contain other ingredients.

What does this mean for your patient?

By building confidence in the therapy, Gloup® contributes towards more effective pharmacotherapy. It is the only Medical Aid that is suitable for taking with all solid medicines. Gloup® is exclusively available in pharmacies.

Gloup® or crushing tablets/ opening capsules?

Tabletten feinmahlen oder Kapseln öffnen – ist das empfehlenswert?

Properties	Swallowing with Gloup®	Crushing tablets or opening capsules	Consequences of grinding / opening
Medical aid or authorized medical treatment?	Yes, Class I	Not usually/ virtually never	Doctor or chemist should prescribe instructions, if not treatment is illegal!
Change in pharmacokinetics?	No	Yes	Affect on effectiveness, absorption speed and quantity dosage can no longer be guaranteed
Increase in contraindications?	No	Probable	Faster and greater availability of active substance
More than one medication at the same time?	Yes	No	Direct mixing of active substances usually not permitted
Risks to nursing staff? ¹	No	Yes, caused by the potential release of fine dust particles	Aerogenic contamination possible Increase in unintended exposure Direct risk with: antibiotics, antiviral and anticancer medication
Unidentified medication?	No	Yes	Risks of administering incorrect medication due to absence of potential visual verification and correct labelling
Doctor or chemist authorization necessary?	No	Yes	Prior written instructions from medical professional
Patient or nursing staff decision?	Yes	Subject to conditions	Always after consultation with / written authorization from chemist

1. When crushing tablets and opening capsules there is a risk that toxic and potentially hazardous substances may be inhaled or come into direct contact with the skin. Both short and long-term exposure to potentially hazardous substances pose a risk to health.

2. Nursing staff take the five correct preventative measures when administering medication. (In a questionnaire from the V&VN Nurse Practitioners, 56% of respondents indicated that this is not always successful). This relates to:

1. The correct medication
2. Administering to the right patient
3. At the right time
4. Using the correct method of administering
5. In the correct dosage

Changing the medication by grinding or opening the surrounding capsule does not address points 1, 4 and 5 and is therefore unjustified. In the V&VN questionnaire, 125 of the 145 respondents indicate doing this despite the above. Even when nursing staff have written permission from a doctor or chemist, they still remain (partially) liable for the treatment.

Gloup[®] or crushing tablets/ opening capsules?



Properties	Swallowing with Gloup [®]	Crushing tablets or opening capsules	Consequences of grinding / opening
Camouflages the taste of pills?	Yes	No	Unpleasant taste no longer masked
Interactions?	No known interactions, universal gel	Increased risk	(Chemical) reactions due to direct contact with active ingredients
Necessary preventative measures?	No	Yes	Five times 'correct' list? ²
Solution Medication Ingestion Problem (MIP)?	Yes	Not usually	Usually requires mixing with vehicle as powder can get stuck in mouth or oesophagus.
Suitable for all permanent medication?	Yes, universal gel	No	Cannot be determined by patient or nursing staff. Chemist has expertise
Microbiological protection?	Yes, 2 months from 2 - 25°C	No	Administer directly after treatment
Effect on gastric acid-resistant encapsulation?	No	Yes	Irritation to throat and stomach, general loss of effectiveness

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Examples of medication and the effects of grinding

Medication type	Several examples	Risks from grinding
Medication with verified release (retard, PL, LA, exel.)	Adalat oros, Adalat retard, Depakine Chrono, Efexor exel, Seroquel XR	Suddenly high dosage, shorter action, contraindications
Gastric-acid	Cardioaspirine, Losec Mups, Nexiam, Pariet, Voltaren EC	Irritation to oesophagus and stomach, general loss of effectiveness
Sublingual medication	Cedocard SL, Temgesic SL	Dosage is lowered, effectiveness is reduced
Melting tablets	Dafalgan odis, Imodium instant, Zyprexa velotab	Loss of effectiveness
Effervescent tablets	Dafalgan effervescent, Losferron effervescent, Zantac effervescent	Loss of effectiveness
Antibiotics	Augmentin, Floxapen, Tavanic, Zinnat	Risk to nursing staff! Mask and gloves compulsory
Anticancer medication	Advagraf, Endoxan, Imuran, Prograft	Should never be carried out by nursing staff! Subject to chemist preparation conditions
Diverse medication	Proscar, lithiumzouten, cytostatica	Do not allow pregnant women to administer!

Source: Opge(p)let – AZ Groeninge Kortrijk (Belgium), Formularia Meppel Hoogeveen

Bronvermelding:

1. Landelijke instructie Voor Toediening Gereedmaken (VTGM) van medicatie in verpleeg- en verzorgingshuizen V&VN, beroepsvereniging van zorgprofessionals, april 2008
2. Formularia Meppel Hoogeveen: <http://www.formulariameppelhoogeveen.nl/02719c99bd0872b01/02719c99c20ab5d05/index.htm>
3. Zakkaartje Vermalen geneesmiddelen, V&VN
4. Protocolen Voorbehouden, Risicovolle en Overige handelingen Toedienen van medicijnen 4, hoofdstuk Medicatieveiligheid, Vilans, augustus 2012
5. Medicijnen toedienen, 5xjuist-lijst pagina 360: <http://www.pearson.nl/download/ProefVerpleegVaarDeel1.pdf>,
6. Opge(p)let AZ Groeninge: http://www.azgroeninge.be/eCache/5233/Apotheek_-_pletmedicatie.pdf

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