EXHIBIT A

Summary of Product Characteristics

Fumaderm® Initial
Fumaderm®

1. Name of the medicinal product
Fumaderm Initial
Fumaderm

2. Qualitative and quantitative composition
The active ingredients of Fumaderm Initial and Fumaderm are:
Dimethyl fumarate;
Ethyl hydrogen fumarate, calcium salt;
Ethyl hydrogen fumarate, magnesium salt;
Ethyl hydrogen fumarate, zinc salt.

1 gastro-resistant tablet contains:

	Fumaderm Initial	Fumaderm
Dimethyl fumarate	30 mg	120 mg
Ethyl hydrogen fumarate, Calcium salt	67 mg	87 mg
Ethyl hydrogen fumarate, Magnesium salt	5 mg	5 mg
Ethyl hydrogen fumarate, Zinc salt	3 mg	3 mg

For excipients, see section 6.1

3. Pharmaceutical Form
Gastro-resistant tablet for oral use.

4. Clinical Particulars

4.1 Therapeutic Indications
Fumaderm Initial:
Indicated to improve patient tolerability to Fumaderm therapy during the start-up phase.

Fumaderm:
Indicated for the treatment of severe forms of plaque psoriasis (*Psoriasis vulgaris*), in cases where previous, externally applied, stand-alone treatments have failed. Prior to administration, patient tolerability must firstly be reinforced by treatment with Fumaderm Initial (q.v.).

4.2 Posology and method of administration
Fumaderm Initial:
Unless otherwise prescribed, dosage instructions are as follows:

In reaching the optimal efficacy and tolerability profile, dose escalation should be gradual. During the first week of treatment, 1 gastro-resistant Fumaderm Initial tablet should be taken once daily (evenings). During Week 2, this daily dose should be increased to 2 gastro-resistant Fumaderm Initial tablets (1 x mornings and 1 x evenings). During Week 3 (daily dose = 3 gastro-resistant

Fumaderm Initial tablets), as soon as the course of Fumaderm Initial tablets has finished, treatment should be immediately switched over to Fumaderm, viz. at an initial daily dose of 1 gastro-resistant Fumaderm tablet once daily (evenings).

Week	Dosage		
	Mornings	Lunchtimes	Evenings
1	-	-	1
2	1	-	1
3	1	1	1

Fumaderm:
Unless otherwise prescribed, dosage instructions are as follows:
Following pre-treatment with Fumaderm Initial to increase tolerability, treatment should be switched over to Fumaderm during the third week of treatment.
During the first week of treatment with Fumaderm, 1 gastro-resistant Fumaderm tablet should be taken once daily (evenings). Depending on individual tolerability, this daily dosage should be increased in weekly increments (i.e. by one gastro-resistant Fumaderm tablet per week), according to the following chart:

Week	Dosage		
	Mornings	Lunchtimes	Evenings
1	-	-	1
2	1	-	1
3	1	1	1
4	1	1	2
5	2	1	2
6	2	2	2

The maximum daily dosage of 3 x 2 gastro-resistant Fumaderm tablets must not be exceeded. However, in most cases, administration of this maximum daily dosage is not needed. Clinical experience has shown that the initial therapeutic effects are noticed within 4 – 6 weeks of treatment.
When skin reactions subside, daily dosage should be reduced gradually until the individual maintenance dose is reached. Fumaderm gastro-resistant tablets should be swallowed whole (not chewed) with plenty of liquid during or immediately after a meal. Patients should be advised to drink sufficient amounts of water during the day (1½ - 2 litres). Duration of treatment is left up to the discretion of the treating physician. Adequate experience gained during clinical trials would suggest a treatment period of four months. However, clinical experience exists of treatment periods of up to 36 months, recorded within the framework of post-marketing observational studies.

4.3 Contraindications
Fumaderm Initial and Fumaderm are contraindicated in the following cases:

- Known hypersensitivity to the active ingredients (dimethyl fumarate; ethyl hydrogen fumarate calcium/ magnesium and/or zinc salt) or any of the excipients used in Fumaderm Initial/ Fumaderm;
- Severe gastrointestinal disease, such as gastric and/or duodenal ulcers;
- Severe hepatic and renal disease;
- Due to the therapeutic risk involved (risk/ benefit ratio), mild cases of *Psoriasis vulgaris*, e.g. circumscribed plaque psoriasis or chronic stationary plaque psoriasis covering less than 10% of total body surface;
- Due to insufficient clinical experience, cases of pustular psoriasis– although isolated case reports would seem to indicate some degree of therapeutic efficacy;
- In patients below 18 years of age;

– During pregnancy and lactation.

4.4 Special warnings and special precautions for use
Prior to initiation of treatment with Fumaderm Initial and Fumaderm, a full blood count (including a differential count and platelets) should be performed. In the presence of values outside the normal range, treatment with Fumaderm Initial and Fumaderm must not be instituted. During the course of treatment, full blood counts (leukocyte count and differential count) must be monitored on a regular basis. Tests should be performed no earlier than 14 days following treatment initiation and within the first three months of therapy. If results from these tests reveal no anomalies, a full blood count (performed on a monthly basis thereafter) is sufficient. Treatment with Fumaderm Initial or Fumaderm should be suspended immediately in the presence of a significant reduction in leukocyte levels – particularly if values should fall below 3000/mm3 — or if there are any other pathologic changes in the blood count. In such events, blood count levels should be monitored until normalisation is achieved. Similarly, prior to and during treatment, the following parameters should be tested (no earlier than 14 days following treatment initiation and within the first four weeks; and every four weeks thereafter) to identify any possible adverse effects on liver and kidney function: SGOT (ASAT) and SGPT (ASAT) activity; Gamma GT; AP; serum creatinine concentrations; proteinuria; urinary sediment. Furthermore, caution should be exercised in the presence of haematological disorders. Therapy should be discontinued in the case of increased creatinine levels above the normal range.

4.5 Interaction with other medicinal products and other forms of interaction
Whilst receiving Fumaderm Initial/ Fumaderm therapy, concomitant use of the following is not permitted: methotrexate, retinoids, psoralens, cyclosporine, immunosuppressants, cytostatics and drugs known to impair renal function. During treatment with Fumaderm Initial/ Fumaderm, concomitant topical application of fumaric acid derivatives (e.g. in the form of ointments and/or baths) should be avoided, as the additional uptake of these derivatives, found in certain ointments and bath formulations, may lead to an overdose as a result of exceeding the maximal tolerable dose.

4.6 Pregnancy and lactation
Although, on the basis of animal experiments, there are no indications of any teratogenic effect, Fumaderm Initial and Fumaderm should not be used during either pregnancy or lactation, as there is a lack of clinical experience regarding use during human pregnancy, and it is not known whether their active substances are excreted in human milk.

4.7 Effects on ability to drive and use machines
When used at recommended doses, it can be expected that Fumaderm Initial and Fumaderm have no effect on the ability to drive or operate machinery.

4.8 Undesirable effects
Undesirable effects have been evaluated in accordance with the following frequency convention:

Very common: (> 1/ 10 of patients treated)	Common: (> 1/ 100 of patients treated)
Uncommon: (1/ 1,000 of patients treated)	Rare: (1/ 10,000 of patients treated)
Very rare: (≤ 1/ 10,000 patients; including isolated cases)	

Undesirable effects and counter-measures

***Skin and subcutaneous disorders*:**
Very common:
– Facial redness and hot flushes
These disorders occur very frequently at initiation of therapy and usually subside during the course of treatment. However, severe manifestations of this kind may necessitate the discontinuation of treatment with either product.

Rare:
– Allergic skin reactions
These disorders are reversible upon discontinuation of treatment.

***Gastrointestinal disorders*:**
Very common:
– Diarrhoea

Common:
– Feelings of bloatedness
– Upper abdominal cramps
– Flatulence

Uncommon:
– Nausea

These undesirable effects are very common at initiation of therapy and usually subside during the course of treatment. In most cases, reduced dosage is sufficient to alleviate these disorders. However, should these effects persist, the treating physician should consider the possibility of discontinuing therapy.

***Nervous system disorders*:**
Uncommon:
– Tiredness
– Dizziness
– Headaches
These side effects usually subside during the course of treatment. In most cases, reduced dosage is sufficient to alleviate these disorders. However, should these effects persist, the treating physician should consider the possibility of discontinuing therapy.

***Blood and lymphatic system disorders*:**
Changes in blood count levels, such as leuko/ lymphopenia and varying degrees of eosinophilia, have been reported (cf. section 4.4: "Special warnings and special precautions for use"):

Very common:
– mild forms of lymphopenia (approx. 50% of patients)
– mild leukopenia (approx. 11% of patients)

Common:
– More severe forms of lymphopenia (approx. 3% of patients)
Signs of lymphopenia and leukopenia may regress. However, they may also repeatedly reoccur during treatment or even progress over the longer term.

Common:
– Transient eosinophilia

Very rare:
– Persistent eosinophilia

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