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A HAPPY BIRTHDAY

Wallace has recently celebrated its 60th Birthday, reinforcing its long-standing position as a pharmaceutical company of excellence.

The core Wallace range consists of over 50 medical specialities. Wallace products are sold in over 90 international territories and are trusted by Hospitals, Doctors, Pharmacists and Patients alike. Wallace products are appropriately licensed by the UK Department of Health (MHRA) and in each country local licensing and approval procedures are followed.

Wallace products are manufactured under GMP (Good Manufacturing Practice) conditions within the United Kingdom benefiting from facilities utilising modern equipment and conforming to UK Department of Health inspection standards.

Wallace is looking forward to the future with energy, enthusiasm and vigour and takes the opportunity to pass forward its best wishes to the Medical and Retail professions.



Taking Part

Wallace and its sister companies have been actively involved in a number of interesting conferences and exhibitions throughout the year. The company has taken part on a truly global scale exhibiting at such events as the 6th Singapore Congress in Obstetrics and Gynaecology held at the Conrad Centennial, Singapore, The Fiji College of General Practitioners (FCGP) and the Fiji Pharmaceutical Society Conference both held at the luxurious Sheraton Resort, the Workshop on Good Pharmacy Practice in Oman together with the 4th Annual Pharma Workshop in Oman, which this year focused on the important topic of Pharmacovigilance.

Looking Good

2007 saw the soft launch of the new Wallace Corporate identity and that of its sister companies. The elegant new logo is already being used on corporate stationery and is being phased onto promotional materials, group websites, and product packaging.

Recognising that across the world, people's needs and expectations are as diverse and varied as the cultures and countries they come from, the new corporate symbol has been designed to reflect a global ideal of quality which translates visually in any language. Its butterfly characteristics communicate the most productive, beautiful state of evolution representing a company whose vision, passion and expertise is to create an experience that never remains static attracting medical professionals and consumers who will want to return again and again.

On Display

Following the successful soft launch of the new corporate identity the company has been assisting one of its East African distribution partners to create new displays for the Wallace products within their pharmacy outlets as well as materials for a new set of hospital based conferences scheduled to run in 2008. Initial feedback has been extremely positive and the company is looking forward to further developing this initiative during 2008.





New Vitality

Wallace's Vitaseng Syrup is quickly establishing itself as the Gold Standard within the arena of nutraceutical liquids. This exciting product benefits from the inclusion of an amazing 19 active ingredients. This powerful tonic is an excellent vitamin and mineral supplement and offers the inclusion of Iron and Ginseng. The syrup is suitable for both adults and children over five years and is available in a convenient 200ml presentation. (Always read the product packaging.)

Keep in Touch

From time to time Wallace would like to keep in touch with Doctors and Pharmacists. We do this through our Medical Representatives but are now embracing the world-wide web to allow a faster more instantaneous delivery. If you are interested in signing up for our newsletter please visit www.alinter-group.co.uk/newsletter

Osteoporosis

Wallace is delighted to advise the pending launch of Osteomed, a new Osteoporosis targeted product which will be available in selected markets during Q1, 2008. Wallace sales representatives will provide further details shortly.



Modern Medicine and Paediatric Digest





Wallace shall be continuing its relationship with both Modern Medicine Magazine and Paediatric Digest during 2008. If you are a Medical Doctor and do not already receive these publications please ask the Wallace Medical representative about the possibility of being added to the publishers mailing list. The publisher is also responsible for the MEPP0 Index in which Wallace also participates.

An overview of antacids and Actonorm Gel

Indigestion (dyspepsia) is a general term covering a group of non-specific symptoms including discomfort in the central upper abdomen, nausea and occasionally heartburn. A common cause of indigestion is excessive gastric acid production and reflux of this acid back upwards into the oesophagus (referred to as gastro-oesophageal reflux disease: GORD).

Sometimes changes in lifestyle are all that are required to alleviate GORD. These include: sleeping on the left side; avoiding food for two hours before lying down; smaller meals and avoiding irritants such as cola, tea, coffee, alcohol and smoking. However, many people find that their symptoms fail to be controlled by lifestyle alone and so need medication to relieve their symptoms. There are four main classes of medication for these purposes LISTED BELOW:



-  **ANTACIDS.** These neutralise gastric acid and so ensure that any reflux in the oesophagus is insufficiently acidic to cause the burning feeling known as heartburn.
-  **BARRIER COMPOUNDS (ALGINATES).** These float on the stomach contents providing a physical barrier to prevent reflux.
-  **INHIBITORS OF ACID SECRETION (HISTAMINE2-RECEPTOR ANTAGONISTS AND PROTON PUMP INHIBITORS).** These reduce acid secretion.
-  **MOTILITY STIMULANTS/PROKINETICS** to increase muscular contractions in the gastrointestinal tract.



FOCUS ON ANTACIDS

Antacids are simple alkalis that neutralise stomach acid for short periods. Examples are aluminium hydroxide, magnesium hydroxide and sodium bicarbonate. Generally, they have few side effects although they can affect the bowels: aluminium-containing antacids can cause constipation and magnesium-containing ones may cause diarrhoea. Some antacids (especially sodium bicarbonate) produce gas as they work and this can cause flatulence. Dimethicone is a chemical that is often added to antacids to reduce flatulence.



CALCIMAX SYRUP

The human skeleton begins with over 300 bones, some of which then fuse together in development, leaving 206 bones in an adult. Bones support the flesh and organs of the body, and joints and muscles allow the bones to move. Calcium, the most abundant mineral in the body, provides much of the strength and weight-bearing capabilities of bone, with 99% of the body's calcium content being incorporated into bones and teeth (the remaining calcium is present in both the intra- and extracellular fluids).

For good bone strength, the estimated average requirement of calcium is 700mg daily and a good proportion of this can be obtained from dietary sources such as those shown in the table:



Food:	Serving:	Calcium (mg):
Whole milk	200ml	220
Semi-skimmed milk	200ml	230
Hard cheese	30g	190
Cottage cheese	115g	80
Low fat yoghurt	150g	225
Sardines (including bones)	60g	310
Brown or white bread	3 slices	100
Baked beans	115g	60
Boiled cabbage	115g	40

A WONDERFUL TRIO

Vitamin deficiencies seldom occur singly and are most marked in growing children and adolescents, lactating mothers, those on weight loss, vegan, vegetarian, or poorly balanced diets, and during and after illnesses. During pregnancy there is often a requirement for additional vitamins but it is important to seek guidance from a doctor or antenatal clinic.*





Actonorm Gel is an effective antacid which contains aluminium hydroxide $Al(OH)_3$, Magnesium Hydroxide $Mg(OH)_2$ and dimethicone as the active ingredients, with $Al(OH)_3$ and $Mg(OH)_2$ balanced in the Gel to have neither a laxative nor a constipating effect. Actonorm Gel achieves its neutralizing effect on gastric acid by the two hydroxides reacting with gastric acid to produce the chlorides of aluminium and magnesium, and this in turn slowly raises the pH to about 4. The dimethicone in Actonorm Gel relieves flatulence, and a double-blind controlled trial has shown that dimethicone also helps to reduce the degree of oesophagitis and ulceration seen at endoscopy (Ogilvie and Atkinson, 1986). Actonorm Gel is a well known and extensively used antacid worldwide.



However, many diets compare poorly to the daily requirement of 700mg, especially given that only 30 to 40% of ingested calcium is normally absorbed from the intestine. For this reason, calcium supplements such as Calcimax Syrup are popular. Calcimax presents in high concentration soluble calcium salts (Calcium Chloride and Calcium Levulinate) which are characterised by their low toxicity and absence of gastric irritation. Calcium Levulinate is used since it is better tolerated by mouth than Calcium Chloride, however solubility considerations preclude all the calcium being present as the Levulinate.

Calcimax Syrup is particularly useful for prophylaxis where there is a tendency to osteomalacia and osteoporosis. In both of these conditions there is a loss of bone density: in osteomalacia this is due to an overall decrease in bone calcification and in osteoporosis due to a reduction in bone matrix and bone formation. The increased bone fracture risk with these two conditions can be reduced by taking a supplement such as Calcimax to strengthen the bones. This is particularly important for older people, as many older people are at risk of developing osteoporosis as due to the reduction in bone mass with age (see graph):

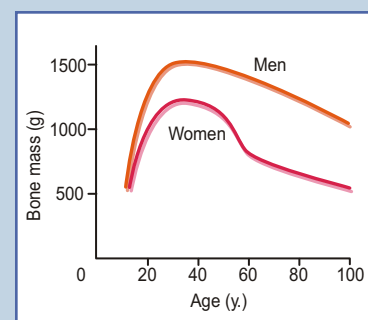


Figure 4.12
Changes in bone mass with age

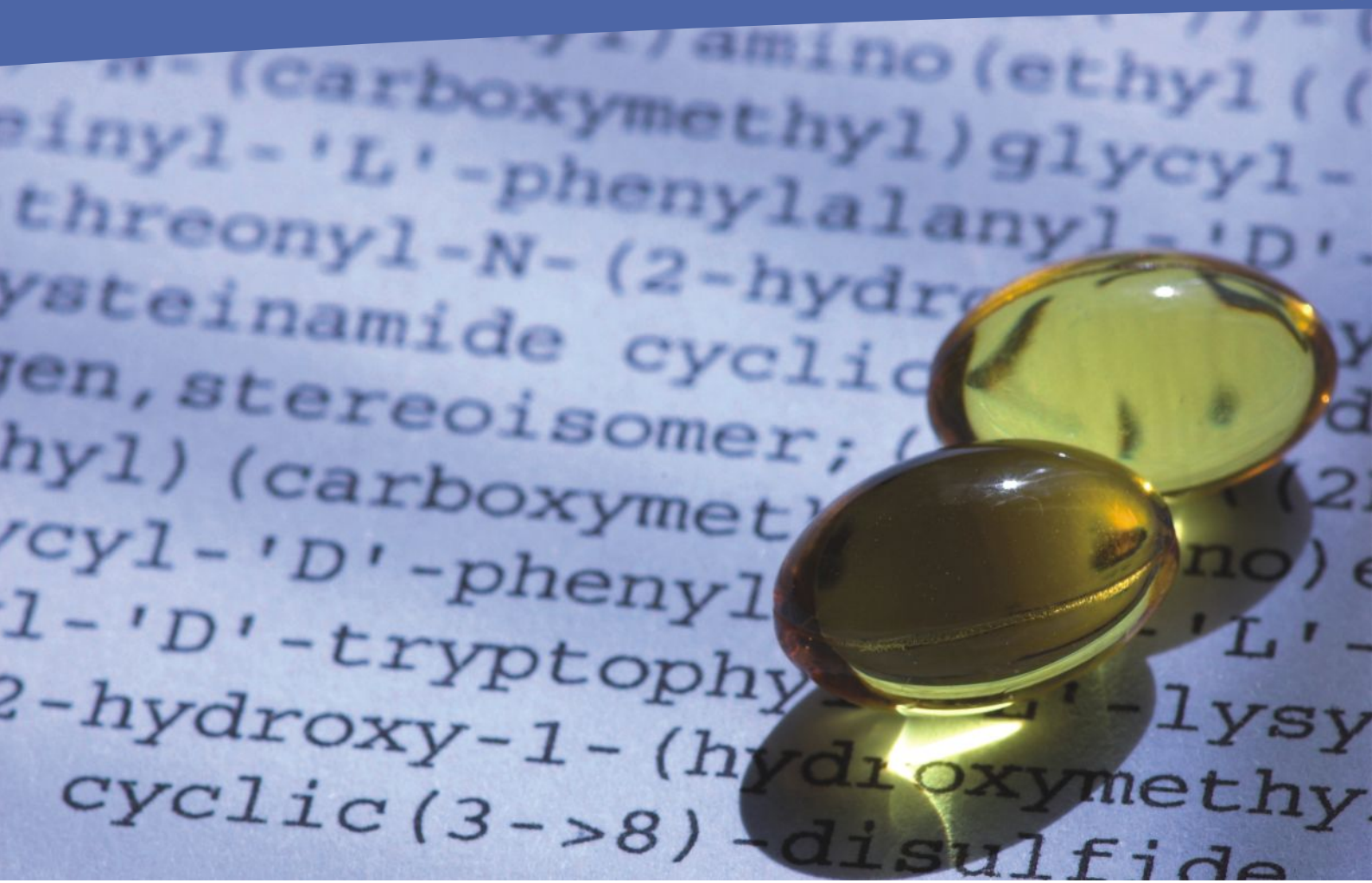
Calcimax Syrup is also useful for younger people, particularly those experiencing increased calcium demand in adolescence, pregnancy, lactation and convalescence. Vitamins of the B and C group are also present in Calcimax as it has been found that there is often a concomitant deficiency of these in calcium deficiency states. The vitamins in Calcimax Syrup may in addition prove useful in vitamin deficiency states such as Wernicke's Encephalopathy, irradiation sickness and Prickly Heat.

CONCAVIT products provide the essential factors required in a dietary supplement to aid the prevention of vitamin deficiencies and are available in three presentations:-

- 🌸 Easy to swallow Soft Gelatine Capsules
- 🌸 Pleasant tasting sugar free syrup (suitable for most well controlled Type I and Type II diabetics)
- 🌸 Concentrated Drops

CONCAVIT DROPS are especially suitable for children and infants. They are highly concentrated to enable them to be mixed into drinks or blended with semi-solid and pureed infants' foods.

** If an individual is pregnant or likely to become pregnant they are advised to consult their Doctor or antenatal clinic before taking vitamin A supplements, as they can advise on the best way to manage the diet and what food combinations will be best. Generally during pregnancy it is best to avoid concurrent use of vitamin A supplements and liver.*



The Alinter Group ADR System

Our group takes the handling of Adverse Drug Reactions (ADRs) very seriously.

ADRs should ideally be reported by health professionals and our website encourages individuals to ask their doctor or pharmacist to make reports on their behalf. This also ensures patient anonymity. We realise that in some circumstances that may be difficult so there are no actual procedures in place to prevent individuals from making personal reports.

Our website includes downloadable ADR forms in English, French, Greek, Arabic, Farsi and Chinese which can be filled in and faxed or emailed to us. However our preferred mechanism of ADR reporting is using the online form.

<http://www.alinter.co.uk/adr>

Our form is kept deliberately brief to encourage the initial ADR report to be made. It contains sufficient information to be collected to determine if the ADR is unusual and/or if further information needs to be requested from the reporter.

For maximum control we have written our own software for the ADR system and it is hosted on our own servers. All data is automatically distributed to the correct departments and also collated in a separate ADR database.

If for any reason the ADR server fails the reporter will receive immediate notification of the fact and will be directed to the downloadable forms held on a geographically separate server.

The screenshot shows the Alinter ADR System web form. It includes a header with the Alinter logo and 'adr system' text. Below the header is a disclaimer: 'This form is to allow a rapid initial report to be made. It is not the primary ADR document. Our Pharmacovigilance Department will review all submitted data and make direct contact with you to gather more information on the suspected ADR if required.' It lists required information: patient identifier, reporter details, reaction details, and product name. The form is divided into sections: A. PATIENT INFORMATION (Patient Identifier, Age, Gender, Weight), B. SUSPECTED ADVERSE REACTION (Date, Description), C. DETAILS OF MEDICAL PRODUCT (Name, Dose, Batch, Concomitant products), D. REPORTER INFORMATION (Name, Address, Phone/Fax, Email, Occupation), and E. NATIONAL PHARMACOVIOLANCE (Reporting to local authority). A 'Submit Report' button is at the bottom.



Pharmacovigilance is the collection and assessment of medicinal product safety data, and is focused upon improving patient safety. Of course, this is not only of benefit to the patient, but it is also important for the Marketing Authorisation Holder (MAH) and the Healthcare Professional. The MAH does not want to be actively marketing a product with unidentified safety issues, and doctors and pharmacists want to be able to prescribe and administer drugs without fear of unexpected serious adverse drug reactions (ADRs).

Pharmacovigilance is about being reactive and pro-active with regard to drug safety. Being reactive includes the thorough investigation of drug safety complaints more of which later. To be pro-active the MAH must seek new safety information; search worldwide published studies and articles, routinely scrutinise all the safety data held about a product and the active substances looking for new safety signals, and present periodic safety update reports (PSURs). The MAH can then routinely reassess the benefit to risk ratio of the product, and ensure their licence data is current and accurate.

As mentioned previously, MAHs must investigate and report ADRs, but Healthcare Professionals and the wider pharmaceutical industry, share in this responsibility. The term 'Healthcare Professionals' in this context includes pharmacists, doctors, dentists, nurses and coroners, and the 'pharmaceutical industry' includes manufacturers, distributors and sales representatives, as well as MAHs. There is a collective responsibility to ensure that ADR information is reported, assessed and used, quickly and thoroughly.

Any untoward medical occurrence in a patient following the administration of a medicinal product, is considered to be an adverse event. An adverse event can include the misuse and abuse of a drug, or a lack of efficacy ("it doesn't work!"). However, if there is a suspected relationship between the adverse event and the medicinal product (causality) it is deemed to be a suspected adverse drug reaction. Either the Healthcare Professional or the MAH may raise the suspicion of a causal relationship between the event and the medicinal product, and they do not have to be in agreement.

Of course, many drugs have expected and accepted side effects, ranging in seriousness and severity. The Summary of Product Characteristics (SPC) details all the expected side effects of a medicinal product, considering known clinical information, the pharmaceutical form and the route of administration. In many cases the SPC will also detail the probability of any given side effect (very rare, common etc.) and the potential seriousness.

An ADR begins with a patient reporting or presenting an adverse event to a Healthcare Professional. It cannot be reported to the MAH by anyone except a Healthcare Professional. If a patient tries to do so, they will be referred back to their doctor or pharmacist. The quality and the speed of the subsequent investigation is largely dictated by the information ascertained and recorded during this initial consultation. The Healthcare Professional is in a privileged position which will not be repeated; they will receive a first hand description of the adverse event, and they may be able to witness the actual event or it will have occurred in the recent past.

The Healthcare Professional is then faced with a choice: report the suspected ADR direct to the MAH or use the 'anonymised' reporting route, direct to a Regulatory Authority. Whenever possible, consideration should be given to reporting the ADR direct to the MAH as this will result in a full investigation, which in itself can only lead to better product understanding and

improved patient safety. Of course this may mean more involvement from the Healthcare Professional, but ultimately this is for their benefit too: they are the front line of drug administration and improved product knowledge and safety will make their jobs easier.

The Healthcare Professional must be aware that in order for an MAH to validate a suspected ADR, the minimum required information is: 1) an identifiable patient, 2) the product name, 3) details of the event, and 4) details of the Healthcare Professional reporting the suspected ADR. However, this should always be considered as the absolute minimum requirement and as much information as possible should be presented, even as a follow up to the initial report. Also, it is always useful to the investigation if original product can be retrieved from the patient, or even just the batch number, so that any potential quality issues can be investigated and discounted if necessary.

A good template of the comprehensive information ideally required to fully investigate an ADR is the CIOMS form (Council for International Organizations of Medical Sciences). The CIOMS form provides a complete picture of the suspected ADR and the patient, including concomitant drug use, suspect drug dosage and period of use, route of administration and any test results. It is particularly important that the Healthcare Professional should try and use standardised medical terms (MedDRA) to describe the event to prevent any misunderstanding by the investigating MAH.

The Healthcare Professional should find it possible to contact the MAH using the current contact information presented on the patient information leaflet or the immediate product packaging. This information can also be used to find a website or e-mail address to help speed up the reporting process. A MAHs staff will be trained to recognise incoming suspected ADR information and to ensure it is passed onto appropriate personnel within their organisation for investigation quickly and completely.

Upon receipt of a suspected ADR the MAH must assess: 1) is the minimum required information present? 2) is it serious? 3) is it expected? 4) where was it reported (EEA, worldwide)? An ADR is thought to be unexpected if it is not listed on the current SPC for the drug. An ADR is classified as serious if it is fatal, results in the (prolonged) hospitalisation of a patient, leads to persistent or significant disability or results in a birth defect.

The initial assessment of the ADR will dictate how the MAH responds. For example, a serious and unexpected ADR must be reported within 15 days of first notification to the Regulatory Authorities where the product is sold in the EEA (expedited reporting). The MAH will report the ADR to each country where the product is licensed or sold, all of whom will have different reporting requirements that must be well understood by the MAH. All ADRs, regardless of immediate reporting requirements, will be added to the collective safety data for the product held by the MAH, to be routinely assessed en masse for new 'signals' and reported in the PSUR.

Pharmacovigilance ensures that the benefit to risk ratio of a medicinal product for a given indication is continuously assessed and remains positive. This is of advantage to everyone - the patient, the MAH and the Healthcare Professional. So, pharmacovigilance itself should also be considered as a 'benefit to effort' ratio, which remains overwhelmingly positive!



BMI Made Easy

We are delighted to have launched our new on-line BMI calculator making calculation simpler than ever.

Simply log onto www.alinter.co.uk/bmi and enter weight and height. Hit "Calculate" and our server will assess the data and plot a graph. The system offers Metric, UK Imperial and US data input options.

alinter group			body mass index calculator		
METRIC		UK		US	
Weight 70 Kg	Weight 11 St. 0.3 Lb.	Weight 154.3 Lb.			
Height 1.7 Metres	Height 5 Ft. 6.9 in.	Height 5 Ft. 6.9 in.			
<input type="button" value="Calculate!"/>	<input type="button" value="Calculate!"/>	<input type="button" value="Calculate!"/>			

Please enter your weight and height.

If the server is busy it can take a few minutes to produce the graph.

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