

Orthoplex Selling Standards



Orthoplex products will only be made available to Clinical Practitioners that comply to the set criteria below.

Purchasing Account

- **A registered Healthcare Practitioner:**
 - A Healthcare Practitioner is described as a person who belongs to the professions or associations described in section 42AA(1)(a) and (c) of the Therapeutic Goods Act 1989 and Schedule 1 of the Therapeutic Goods Regulations 1990.
 - To access our Orthoplex products, qualified Healthcare Practitioners must hold a Bachelor's degree post December 2022 or relevant qualifications (i.e. Advanced Diploma) pre-Dec 2022 from a Registered Training Organisation. A relevant Bachelor's degree (i.e. in a Medical or Health Science field) is also acceptable.
 - Must hold the purchasing account either personally or through a registered practice.
 - Must hold a current TGA Exemption Number/Indemnity Insurance if practising as a Herbalist, Homeopath, Naturopath or Nutritionist.
 - Must inform Bio Concepts and their distributor/s if a practitioner leaves the clinic.
- **Students:**
 - In their final year/s on presenting evidence of their education status and undertaking of practical clinical studies, may purchase products for educational and/or personal use.

Bio Concepts reserves the right to approve or reject a Healthcare Practitioner at their discretion.

Consultation for Orthoplex White

- A consultation can only be conducted in an enclosed or dedicated seating area where privacy must be assured. It is at the discretion of Bio Concepts to determine the adequacy of this area.
- The consultation is to be as per industry standards as a minimum.
- The initial consultation should be face to face if possible, however if telehealth is the preferred method for consultation, this can be done via the telephone or internet.
- The initial consultation, as a minimum should be paid for by the patient.
- An over the counter or shop floor consultation does not qualify as a consultation.
- A questionnaire alone does not qualify as a consultation.
- Any walk-in patients must undergo a full consultation.
- At the conclusion of a consultation a script or written usage instructions (see Definitions section) is made available to the patient for each product prescribed and/or dispensed.
- Up-to-date clinical records must be maintained on all patients in a safe and secure area. These records should include copies of all scripts or written usage instructions.
 - A practitioner should prescribe a product only to their patient, or after receiving a VALID script. Prescribing to only their patient is best practice to maintain continued monitoring of the patient's health condition and prevents doubling up of supplements.

Dispensing

- **Products can only be dispensed:**
 - After a consultation from a registered Healthcare Practitioner and / or
 - On the sighting of a valid script (see *Definitions*) issued by a registered Healthcare Practitioner.
- The sighting of a valid script is proof that a consultation has been correctly conducted by a registered Healthcare Practitioner.
- An administration assistant within a Clinic can dispense a product when presented with a valid script issued by that Clinic. If the valid script is from another Clinic, then the Healthcare Practitioner is to dispense the product.
- No one must dispense a script that has expired, is not dated and / or neglects to offer any instructions on how to use the products. If there is any doubt to the validity of the script, then no products should be dispensed.
- Only the number of repeats indicated on a valid script is to be filled. If the patient requests additional repeats when not specified on a script, then they should be referred back to their Practitioner for advice and no products dispensed.
- Students in their final year/s (including those in their third and fourth year of study) can dispense products if they are under the supervision of an educational facility or working in a clinic that abides by our brand Selling Standards.

Adverse Reactions

- Patients are to be advised by the Healthcare Practitioner about what to do in the event of an adverse reaction.
- Safety first: If a patient reports an unexpected and unwanted reaction possibly associated with a Bio Concepts product, we would like to hear about it. Please contact our Clinical Support team on 1800 077 113 or email clinicalsupport@bioconcepts.com.au

Product Instruction Labels

- We strongly endorse the Best Practice of all Healthcare Practitioner's to comply to the TGA regulatory guidelines for Practitioner Only Products which states that all dispensed products must have an affixed Instruction Label (see *Definitions* section).

Accessibility (Physical)

- All Orthoplex products must be inaccessible to the general public in a retail-based clinic environment.
- Due to limited availability of storage space, refrigerated products may be stored in an accessible retail fridge, but must be out of view to the general public (e.g., stored within a box).

Visibility (Physical)

- Orthoplex White products must be out of view to the general public in a retail environment.
- No signs or logos relating to Orthoplex White products are to be displayed in a retail area.

Visibility (Online)

- All Orthoplex products are not to be represented on any online platforms (including websites and social media) to the general public, other than on websites, social media and other online platforms controlled or authorised by Bio Concepts.
- Approved distributors for Bio Concepts' products may use online platforms (including websites and social media) as long as the products are displayed in a password protected area for registered Healthcare Practitioners only.
- Registered Healthcare Practitioners may use an online platform to service their own customers as long as this in a password protected area.
- Under no circumstances should any product reviews or testimonials appear on any online platform for Orthoplex products.
- In all circumstances, for the Orthoplex White range, there is to be no visibility of products, no product information, no pricing information, no dosage, and no ingredients visible to the general public. Orthoplex White can only be purchased by the patient once a full consultation has been performed.

Non-Clinic Dispensing

- At the discretion of Bio Concepts, an outlet without a clinic may range these products to service script dispensing.
- The products are to be inaccessible and out of sight of the general public.
- These outlets cannot consult, prescribe, or write a script for Orthoplex White products.
- Only a registered Healthcare Practitioner can dispense the products.
- A registered Healthcare Practitioner must be on staff for all opening hours.

Duty of Care

- We recommend that you seek independent advice about your requirements as a registered Healthcare Practitioner prescribing and dispensing Practitioner Only Products.
- This advice should consider any rules or regulations within the Therapeutic Goods Administration, your Association and any Federal or State Laws.

For any breaches, Bio Concepts reserves the right to cease supply until further investigation has been conducted or for an indefinite period.

Any complaints can be directed to complaints@bioconcepts.com.au

Definitions

Health Profession:

A Healthcare Practitioner is described as a person who belongs to the professions or associations described in section 42AA(1)(a) and (c) of the Therapeutic Goods Act 1989 and Schedule 1 of the Therapeutic Goods Regulations 1990.

Orthoplex White Approved Modalities:

- Acupuncture
- Chiropractor
- Dentist
- Dietitian
- Herbalist
- Homeopath
- Medical Doctor
- Medical Specialist
- Midwife
- Naturopath
- Nurse (registered)
- Nutritionist
- Optometrist
- Osteopath
- Pharmacist
- Physiotherapist
- Psychiatrist
- Psychologist
- Traditional Chinese Medicine
- Other

Professional Association:

- AHPRA
- ATMS
- CMA
- ANPA
- ANTA
- NHAA

For full list of professional associations please go to tga.gov.au

Valid Script:

A valid script should contain:

- Clinic name, location, and contact details
- Prescribing practitioner name, location and contact details
- Date of issue
- Patients name and contact details
- All products to be used by the patient
- Dosage and directions for each individual product (e.g., one tablet three times/day with food)
- Number of repeats, if any, by individual product
- Signed by the issuing practitioner

A valid script cannot:

- Be a screenshot, or image of a patient ordering platform

Written Instruction:

A written instruction should contain:

- Clinic name, location and contact details
- Prescribing practitioner name, location and contact details
- Date of issue
- Patient name and contact details
- All products to be used by the patient
- Dosage and directions for each individual product (e.g., one tablet three times/day with food)

Instruction Labels:

An instruction label should contain:

- Name and contact details of the prescriber
- Name of the patient
- Date of issue
- Dosage and directions for taking
- Number of repeats
- Script reference number (if applicable)